Nova

USER'S MANUAL
Rev. G

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CE 1936

This device is compliant with Directive 93/42/EEC applicable to medical devices. Its compliance has been verified in accordance with the requirements of standard CEI EN 60601-1.

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1. INTENDED USE AND GENERAL INFORMATION FOR THE “NOVA”

NOVA is an active Class IIb therapeutic device (according to the definitions of Directive 93/42/EEC) designed for medical therapy through hyperthermia for physical rehabilitation. Therefore, it is intended to be used under medical supervision.

The Hypertemia, in this case Physio Hypertermia, is a physical therapy that develops endogenous heat of controlled intensity and depth, through the irradiation of high frequency electromagnetic energy and control of the surface temperature of the tissues through stabilization with an exogenous heat source with a water cushion.

The field of use extends from sports traumatology to aging degenerations: contractures, muscle injuries, tendinitis, hematomas, overload damage, post-traumatic pain, arthrosis etc.

The main short-term clinical effect is a more rapid reduction of inflammation and therefore of the painfulness and stiffness of the part to be rehabilitated, which thus can also be effectively moved much earlier and with less discomfort / suffering for the patient, offering him better quality. of life during the rehabilitation process and a better and faster recovery of impaired functionality.

The characteristic therapeutic principle of all these devices is the heat whose impact on human biological tissues has been known for many years. In this regard, it is considered appropriate to recall the CAP 13 of a classic text of Physiotherapy; that chapter DIATERMIA E TERAPIA CON IL CALDO ED IL FREDDO SUPERFICIALE” - Justus F. Lehmann – Barbara J. De Lateur, attached to this document, it summarizes the effects of heat on the human body in the following aspects:

- Increased collagen extensibility
- Pain relief
- Reduction of joint stiffness
- Reduction of muscle spasm
- Increased blood flow
- Reduction of infiltrates, inflammatory, edema and exudates.

Based on these characteristics, the main clinical indications for hyperthermia instruments such as Nova can be identified; in particular:

MUSCULAR PATHOLOGIES
TENDON PATHOLOGIES
OSTEO CARTILAGINEE PATHOLOGIES
SERO BAGS AND BANDS
NEURAL PATHOLOGIES

This manual provides reference information on the use and maintenance of the device to operators. Always follow all the warnings and instructions provided in this manual.

During installation, Easytech offers medical staff a training course on the operation, maintenance and optimum therapeutic use of NOVA.

Essential performances

The device has no life support function for the patient. None of its functions is indispensable.

RESPONSIBILITIES OF EASYTECH

Easytech shall not be liable for the safety and performance of NOVA if:

- Installation, modifications, maintenance and inspections are not carried out by personnel authorized by Easytech.
- The device is installed in a room where the electrical system is not compliant with the requirements applicable to Group 1 medical environments (standard CEI 64- 8/7).
- The device is not used for the intended use or in accordance with the instructions provided in this manual.

Easytech also reserves the right to modify this manual and the technical specifications of the product, that do no affect security, without prior notice.

2. SAFETY INSTRUCTIONS

2.1 GENERAL

NOVA has been designed and manufactured in compliance with Directive 93/42/EEC and in particular with standard CEI EN 60601-1, " Electro-medical equipment – Part 1: general safety regulations".

However, the safety of patients and operators can be guaranteed only if the instructions concerning installation, warnings and regular inspections are duly followed. The following paragraphs detail the warnings and precautions divided into specific topics.

This device is intended to be used by qualified personnel only.

2.2 WARNINGS CONCERNING INSTALLATION, MAINTENANCE AND REGULAR INSPECTION

- Before installing the device, verify that the packaging and contents are not damaged.
- As the device has applied parts intended for use outside the patient The room where the device is installed must be equipped with an electric system compliant with standards CEI 64- 8/7 Sect. 710 and classified as "Group 1 medical environment".
- Verify that the power supply complies with the requirements specified on the device nameplate.
- In particular, verify that the wall outlet is fitted with a ground connection.
- Only use the power cable supplied with NOVA or at any rate spare cables supplied by Easytech. Although there are several similar and good quality commercial cables, these seldom have the characteristics required to guarantee full compliance with the standards to which the device complies. In particular:
  - An insufficient lead section, excessive length or both these characteristics together, do not guarantee the compliance with the required safety standards.
  - Furthermore, as stated in standard EN 60601-1-2 regarding electromagnetic compatibility, "the use of cables other than those specified.....may increase emissions or reduce the immunity of the device".
- Do not use adapters, multiple sockets or patch cords to connect NOVA to the mains.
- Do not place heavy or sharp objects on the power cable to avoid damaging it.
- Do not install Nova next to heat sources. The device should be installed in an adequately ventilated location.
- Do not install the device in areas where it could be exposed to sudden temperature and humidity variations, dust, chemical vapors, impacts and vibrations.

- Nova is not an AP or APG category appliance, therefore it cannot be used in the presence of anesthetics or other flammable substances.

- Do not install the device next to equipment that could generate electromagnetic interference (such as portable and mobile communication devices, or electro-medical devices that use electromagnetic energy for therapeutic or diagnostic purposes) above the Normative recommended limits, which could affect the device immunity.

- Do not install the device next to other equipment, and specifically electro-medical equipment, that could absorb the electromagnetic interferences produced by NOVA during the therapy.

- Follow the instructions provided in Chapter 7 for maintenance, calibration and regular inspections.

- "WARNING: Do not modify this device in any way without the manufacturer's authorization."

- "WARNING: In case of modification of the device, appropriate examinations and tests must be carried out to ensure its continuous safe use."

2.3 CAUTIONS FOR USE

- The device must be used only by qualified personnel who has achieved at least a High School Diploma and a Bachelor Degree in Physiotherapy (Short cycle).
- It is useful a good level of knowledge in the use of physical means in physiotherapy and some experience gained from other similar products related to musculoskeletal disorders and in general relevant rehabilitative treatments, in order to understand the potential of the device in question.
- An adequate knowledge of the local language is required.
- Only slight visual or sensory impairments are admitted. Also a slight motor impairment is permitted provided that the correct positioning of the device with respect to the patient is guaranteed.
- Only use the device with the surface temperature sensor supplied by EASYTECH.
- Never remove the casing of the radio frequency generator with the machine on to avoid risks of exposure to radio frequency.
- Always refer to Chapter 7 for maintenance and cleaning operations.
- Do not spill or spray liquids onto the device.
- Do not block the ventilation outlets or insert objects into them.
- Always verify that the applicator of the hyperthermia module and the bolus (that is the external bag) are not damaged. Immediately replace the bag with a new one in the event of leakage.
- Frequently inspect the device, its power cable and the related connectors, verifying in particular that there are no blackened pins, evidence of overheating, mechanical deformation or breaking, or damaged sheaths. This is a simple and fast operation that does not require an extensive inspection of the device, but often enables you to promptly detect a condition that may lead to a failure of fault.

- If the device has fallen, the external casing is damaged or you suspect that the device is not working correctly, contact Easytech's Technical support.
- Chapter 5 provides useful information on how to troubleshoot foreseeable and detectable faults (that are signaled by the device).

2.4 ELECTROMAGNETIC RADIATION SAFETY

NOVA is a device that generates non-ionizing radiation for therapeutic use.
It is therefore mandatory to take all the necessary precautions to make sure that the exposure levels of the operators and patients are maintained below the limits specified in the applicable standards.
It is equally important, as explained in paragraph 2.2, to take all the precautions required to minimize the risk of interferences to other equipment.
This can be done by using the device at appropriate safety distances, which can be calculated on the basis of the data provided below.
Several measurements taken with the applicator correctly positioned on the part to be treated, with the device set to maximum power and placed in the most favorable position, indicate that the power density dispersed in the surrounding environment is below:

0.5 mW/cm^2 (44 V/m) at 30 cm from the applicator
0.2 mW/cm^2 (28 V/m) at 50 cm from the applicator
0.1 mW/cm^2 (20 V/m) at 70 cm from the applicator
0.01 mW/cm^2 (6 V/m) at 2 m from the applicator
0.0024 mW/cm^2 (3 V/m) at 4 m from the applicator

By comparing these values with those of the standards, it is possible to define the safety distances that must be maintained from the device in order not to exceed the exposure limits for operators and people, and prevent interfering with other sensitive equipment.
In particular:
The level of 0.5 mW/cm^2 (minimum measuring distance, at a few centimeters from the applicator) should be compared with the value (1 mW/cm^2 and 62 V/m) of Directive 2013/35/CE of the European Parliament and Council of June 26th 2013 concerning the exposure of personnel. The level of the Directive is mainly based on the thermal effect because, at the frequency used for hyperthermia, all other effects, like those on the cardiovascular and central nervous systems that may occur at much lower frequencies, are negligible, that is not perceived. To have a rough but semi-qualitative idea, this effect is 20 times lower than the one (10 mW/cm^2) that corresponds to a modest sensation of heat and 200 times lower than the heat we perceive when lying in the sun (100 mW/cm^2). To maintain this level, it is sufficient to avoid touching the bolus of the hypothermia module while the device is generating radio frequency. It is also important to note that the power output of the device is almost never equivalent to the maximum values referred to in these measurements, but below half of these values.
The level of 0.2 mW/cm^2 is the value specified in the Recommendation of the European Council of July 12th 1999 for the exposure of people. As explained above, it 50 times lower than the value (10 mW/cm^2) that corresponds to a modest sensation of heat and 500 times lower than the heat we perceive when lying in the sun (100 mW/cm^2). It is sufficient to maintain a distance above 50 cm from the applicator to be exposed to a significant lower level.

The level of 0.1 mW/cm^2 is the generic limit specified in the Decree of the Minister's Council of July 8th 2003 (Italy) regarding the exposure of people to the electromagnetic fields generated by fixed sources like television and radio communication equipment.
The level of 0.01 mW/cm^2 is quoted in the Italian directive as critical level and as quality target as regards to the exposure of people. It is basically the level that has to be maintained in areas that are frequented by many people. Although this limit and the previous one are not specifically related to electro-medical equipment, we believe it is important to quote them in order to highlight the fact that a beam issued at 70 cm- 2 meters from the device produces an electromagnetic field that is equivalent to the one generated by a television set or mobile phone.
The level of 0.0024 mW/cm^2 (3 V/m) does not refer to people, but to equipment.
It represents the maximum noise that electro-medical equipment is expected to tolerate and within which it is able to guarantee optimum performances.

From the described measurement conditions it is evident that it is important to take the following actions in order to ensure that the required maximum distances are not exceeded:

- Position the device so as to minimize the dispersion in the environment (see instructions).
- Always disconnect the device from the power supply before lifting the applicator from the part being treated.
- Always verify that the device and the sensor with the thermocouple are correctly positioned on the part to be treated before starting the treatment (see instructions).

It is important to note that none of the values specified applies to the patient who, for the very reason of being exposed to the therapy, is exposed to much higher values (for a period of time that is much shorter than the typical one of an operator). However, it is good practice:

- To position the hyperthermia applicator so as to minimize the irradiation on body parts that are not to be treated (see instructions).
- Not to start the treatment before the thermoregulation fluid in the bolus bag reaches the desired temperature.

As for the risk of electromagnetic incompatibility between NOVA and other equipment installed in close vicinity, it is advisable to consult the following tables, prescribed by standard CEI EN 60601-1-2, for information on the type of "electromagnetic environment" (levels of electromagnetic fields, safety distances that have to be maintained between equipment) required to minimize the likeliness of these events occurring.

The expression electromagnetic incompatibility indicates the interference produced or absorbed by another device. These interferences are obviously unacceptable if they jeopardizes the safety or main functions of the device. The guidelines in the tables can be used to reduce the likeliness of incompatibility issues to an acceptable level.

ATTENTION

NOVA is a Class A product. In a residential environment this device can cause radio interference: in this case the user may have to take adequate countermeasures.

Safety regarding emissions (EN 60601-1-2)

Manufacturer's guidelines and declaration – Electromagnetic emissions

NOVA is designed to be used in electromagnetic environments with the characteristics specified below. The customer or user shall always have to verify that it is used in the specified environment.

Emission test	Compliance	Electromagnetic environment - Guidelines
RF Emissions – CISPR 11	Group 2	NOVA produces electromagnetic energy for its default internal functions and can therefore affect the operation of other equipment, installed close to it.
RF Emissions – CISPR 11	Class A	NOVA can be used in all types of buildings, including those for residential use and those directly connected to low voltage networks that supply power to buildings used for residential purposes.
Emission of harmonics IEC 61000-3-2	Compliant	
Emission of voltage fluctuations/flicker IEC 61000-3-3	Compliant	

Safety in relation to immunity (EN 60601-1-2)

Manufacturer's guidelines and declaration – Electromagnetic immunity

NOVA is designed to be used in electromagnetic environments with the characteristics specified below. The customer or user shall always have to verify that it is used in the specified environment.

Immunity test	Test level	Compliance	Electromagnetic environment - Guidelines
Electrostatic discharges IEC 61000-4-2	+/- 8 kV, contact +/- 2,4, 8, 15 kV, air	Compliant	Floors must be in wood, cement or ceramic. If the floors are coated with synthetic material, relative humidity should be at least 30%.
Fast transients/bursts IEC 6100-4-4	+/- 2 kV, 100 kHz for power supply lines	Compliant	The quality of the supply voltage must be equivalent to that of a typical commercial or hospital environment.
Surge IEC 6100-4-5	+/- 0.5 kV, +/- 1kV in differential mode +/- 0.5 kV, +/- 1kV, +/- 2 kV in common mode	Compliant	The quality of the supply voltage must be equivalent to that of a typical commercial or hospital environment.
Voltage losses, short interruptions and voltage fluctuations on the input supply lines IEC 6100-4-11	0% drop, 0/5 periods, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% dip, 1 period 70% dip, 25/30 periods	Compliant	The quality of the supply voltage must be equivalent to that of a typical commercial or hospital environment. To ensure a continuous operation, even in the event of power failures, it is advisable to connect the device to a UPS or batteries.
Magnetic field at the mains frequency (50/60 Hz) IEC 6100-4-8	30 A/m	Compliant	

EN 60601-1-2, paragraph 6.8.3.201 a), table 204

Manufacturer's guidelines and declaration – Electromagnetic immunity

NOVA is designed to be used in electromagnetic environments with the characteristics specified below. The customer or user shall always have to verify that it is used in the specified environment.

Immunity test	Test level	Level of compliance	Recommended distance from the interfering source in meters
			RF portable and mobile communication equipment should not be used close to NOVA (and to its cables), at distances below the recommended safety distance, which has been calculated with the following equations and in function of the transmitter frequency.
Conducted RF IEC 6100-4-6	From 150 KHz to 80 MHz	3 Veff (criterion A)	d = 2 x √P
	6,765-6,795 MHz 13,553-13,567 MHz 26,957-27,283 MHz 40,66-40,70 MHz	6 Veff	d = √P
Radiated RF IEC 6100-4-3	80 MHz ÷ 800 MHz	3 V/m (criterion A)	d = 2 x √P
(see note)	800 MHz ÷ 2.5 GHz	3 V/m (criterion A)	d = 2 x √P

In the above equations, "d" is the recommended safety distance in meters and P is the maximum rated output power of the transmitter (in Watt), as provided by the manufacturer. x is the multiplication symbol; √ is the square root symbol.

Interference may occur close to equipment with the following symbol:

2.5 SPECIAL INSTRUCTIONS FOR THE OPERATOR

During the different phases of the treatment, operators must comply with the following instructions:

- Supervise the treatment in order to be able to take timely action if required.
- Use the device in compliance with the instructions contained in this manual and avoid operations that may jeopardize their safety and/or that of patients.
- Position the temperature sensor correctly, that is in compliance with the instructions provided.
- Position the (hyperthermia) applicator on the part to be treated in order to obtain the best possible electromagnetic matching. This will optimize the treatment and help minimize electromagnetic pollution in the environment; this will be accomplished more easily by helping the patient to a comfortable, relaxed position with the treated area facing upwards, so that the applicator may be positioned facing downwards and kept in position against the skin by simple gravity.
- Always maintain the required safety distances during the active treatment phases.
- Pregnant women should avoid standing close to the device during the active treatment phases.
- People wearing pacemakers or other implanted electrodes should not stand close to the device during the active treatment phases.
- Operators wearing hearing aids may use NOVA, provided that they remove their implant or that it has been positively ascertained that it can be safely used with NOVA.
- Operators wearing contact lenses should maintain their eyes at a minimum distance of 30 cm from the device during the treatment.
- Never orient the applicator directly towards the eyes or in the immediate vicinity (this applies both to operators and patients).

2.6 SPECIAL INSTRUCTIONS FOR PATIENTS

2.6.1 Contraindications

According to current information, NOVA should not be used to treat patients suffering from the following conditions:

- Patients suffering from cancer, in particular in presence of metastases
- Patients suffering from serious cardiac diseases
- Patients suffering from bone tuberculosis
- Patients with pacemakers or other implanted electrodes
- Patients with acute infections
- Pregnant patients
- Female patients during the menstrual cycle, specifically if the treatment involves has to be carried out in areas at risk of bleeding
- Patients with acute skin diseases
- Patients with growth plates. Although there is currently no evidence of known negative effects, it is not possible to exclude their occurrence over longer periods of time and therefore state that the device is safe. For precautionary purposes, it is therefore generally safer not to use the device in these cases.
- Diabetes with vascular problems
- it is not recommended to treat very young subjects, in whom the quality and speed of recovery normally do not need help, while on the other hand there is no total certainty of the absolute harmlessness of the therapy, so the risk / benefit ratio does not it is

considered advantageous. This means that the use of the device is not indicated for pediatric patients.

2.6.2 Special precautions

NOVA may be used under continuous medical supervision, provided that the treatment is immediately interrupted in the event of side effects and in the following cases:

- Obese patients
- Patients with ischemic tissues
- Patients with reduced sensitivity to pain
- Patients with prostheses or other implants, if the treatment has to be carried out close to the area where the prosthesis or implant is applied
- Patients likely to suffer from hemorrhage
- Patients suffering from thrombosis
- Elderly patients with frail skin
- Unhealed skin lesions

It is also important to:

- Not to treat testicles and ovaries with hyperthermia, although the ovaries are well protected by the overlaying muscles.
- Avoid simultaneously using ionizing radiation devices because of the additive effect that may arise in combination with NOVA.

2.6.3 Cautions

The following cautions must always be taken into due consideration:

- Time specifications should take into account existing swelling: hyperthermia is not usually recommended in the acute phase (48-72 hours from the event) and must be used with utmost care and at minimum intensity (see guidelines).
- Patients wearing hearing aids may be treated with NOVA only after said devices have been removed.
- Patients wearing contact lenses should maintain their eyes at a minimum distance of 30 cm from the device during the treatment.
- Never orient the applicator directly towards the eyes or in the immediate vicinity.

2.7 SAFETY DEVICES

NOVA is supplied with a control software that continuously monitors its operation, checks that the values of the selected and measured parameters are consistent with one another, and that each of them is within the acceptable range.

If an accidental power failure occurs on the 220 V mains, the device enters the standby mode and must be restarted manually.

The device is also fitted with safety devices that operate independently from the control software and that are designed to stop all the functions of the device:

- Automatic maximum current device for protection against over-current (FUSES).
- Device to protect the thermoregulation fluid from over-temperature. When required (loss of control and consequent high temperature), this device stops the flow of current in the heating resistor. The device resets (that is resumes the supply of current to the resistor) only when the temperature falls below the operating temperature (which is approximately 35°C). If this problem tends to occur frequently, contact the Customer Service.
- Device to protect the end generator power amplifier from over-temperature.

3. DESCRIPTION OF THE DEVICE

3.1 GENERAL OPERATING PRINCIPLES

In order to produce hyperthermia, the device "interacts" with the body mainly in two different ways: by supplying energy to heat the tissues and by measuring the level of heating achieved in order to correct the deviation between the current and desired temperatures.

Although it is not possible to measure the temperature directly on the internal points where the hyperthermia effect occurs (at this would require inserting needles, which would not be feasible with this type of treatment), it is possible to estimate it with a reasonable accuracy, provided that the following conditions are met:

- The forms of energies used and the methods by which they are applied to the tissues generate heat in depth, which is as consistent as possible and above all "predictable".
- Temperature measurements, though not internal, are carried out on an appropriate number of suitable points and can therefore be regarded sufficiently accurate.
- The current information available on the biophysical mechanisms of hyperthermia enables to estimate the internal temperature on the basis of the amount of heat applied and temperature measured. This information is integrated in part into the device, that is in the general programming settings of the microprocessor, but also outlined in the guidelines and in all documentation related to the treatment of specific pathologies and patients.

Theoretical studies and experimental findings show that it is essential to observe the following indications in order to achieve the level of temperature increase and control required for the use of hyperthermia for physiotherapy applications:

- The most appropriate level of heating (a deep, consistent and predictable heat) can be attained by combining two energy sources: an endogenous source with a high penetration power and an exogenous heat source that is able to effectively stabilize superficial temperature.
- The best endogenous source appears to be an electromagnetic wave at a frequency of 433,125 MHz. Frequency is very important because it ensures the required penetration depth. The fact that it is a wave is equally important because the electric field is mainly parallel to the different tissues encountered. This means that it is possible to apply a greater amount of energy to layers with a higher perfusion (like muscles), which are also those able to cool down and thus contrast the increase of temperature. These elements are essential to determine the depth and consistency of heating.
- The best exogenous source appears to be a pad of thermo-regulated circulating liquid, which is placed into contact with the part to be treated.
- A single device (applicator) must be used to simultaneously apply both types of energy.
- It is necessary and generally sufficient to measure the liquid temperature of the exogenous source and the temperature of the sensor applied to the skin surface next to the area that corresponds to the highest electromagnetic energy output, provided that is a single area and that it is centered as compared to the physical area of the applicator that the exogenous source is able to guarantee maximum output in this point; that the thermal coupling between the sensor and liquid and the sensor and underlying tissues is known; and above all that the measures are sufficiently accurate.

If these principles are correctly applied, it is possible to achieve the level of temperature control required for hypothermia applications. Figure 3.1 illustrates four examples of the different results that can be achieved with different types of heating. Curves "a" and "b" can be attained only with a device that meets the hyperthermia requirements described above and respectively refer to a situation in which heat is applied in depth and to one in which it is preferable to treat superficial layers only. Curve "c" represents the maximum level of heat that can be attained with a device with an endogenous source only, while "d" is the maximum heat that can be attained using an exogenous source only. It is obvious however that hyperthermia devices can also produce "c" and "d" types of heating.

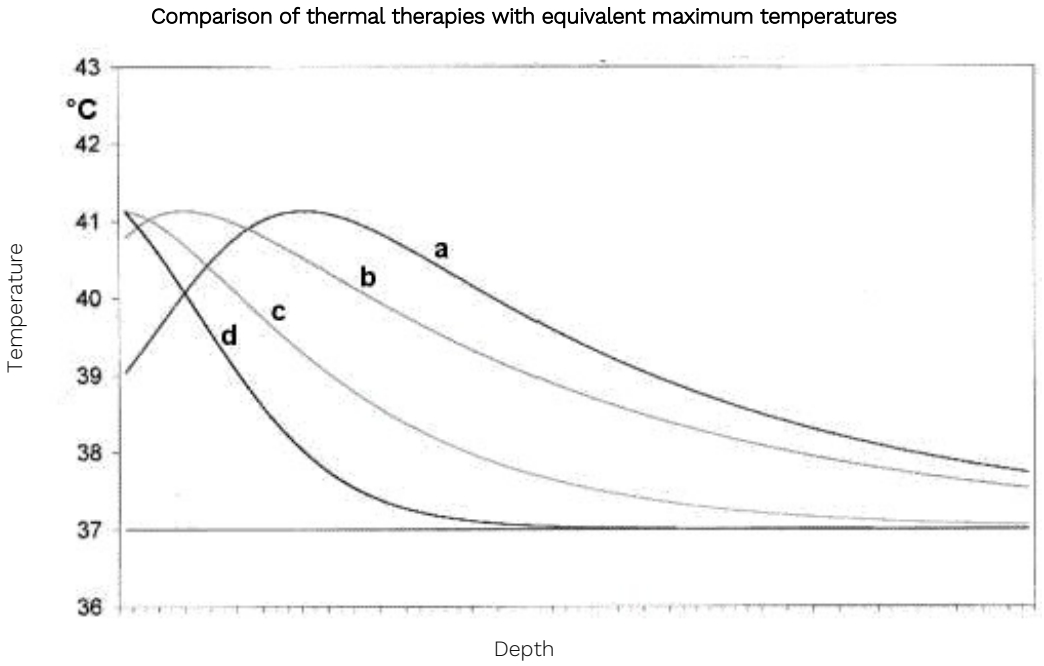


Fig. 3.1 – Cases obtainable with different heating methods

3.2 DESCRIPTION OF THE DEVICE AND ITS FEATURES

With reference to the general principles described above, ***NOVA*** is essentially constituted by the following components:

- A generator that outputs electromagnetic power (RF) at an average frequency of 433,125 MHz in the ISM band, which represents the endogenous source (the electromagnetic energy propagated through the tissues is gradually converted into heat, which is then released within the tissues).
- A module with thermo-regulated circulating liquid (containing deionized water), generally referred to as "thermoregulation" liquid , which represents the exogenous source (the energy that is already in the form of heat, which can be added or subtracted depending on the applied physical conditions, is transmitted to the tissues from the outside, also through the contact with the body surface.
- An applicator that can apply both types of energy to the desired area, consisting of an aerial filled with deionized water to optimize the dimensions and transfer of electromagnetic energy to the tissues, and by a pad containing deionized water coming from the thermostatic module. All these items are integrated in the same assembly.

The pad with its liquid content is generically referred to as "bolus". The aerial section of the applicator uses a coaxial cable to transform the electromagnetic energy coming from the generator into an electromagnetic wave that irradiates through the tissues.

- A sensor to measure the liquid temperature of the exogenous source.
- A sensor with double thermocouple to measure temperature differences, also referred to as DeltaT, between the liquid and the bolus-skin interface. This type of measurement approach offers better results as compared to the absolute measurement of temperature described above, because it enables to estimate internal temperatures with a greater accuracy. This method is currently being patented.
- A "main board" with microprocessor that acquires the signals generated from different parts of the device (for example the two temperature measurements) and transmits the piloting signals required to generate and control hyperthermia.
- A Panel PC equipped with a touch-screen display that is the interface through which the operator enters the treatment parameters and monitors the status of the apparatus (and, therefore, of the treatment).
- A power supply connected to the 220 V AC mains.
- A bracket to support and position the applicator.
- A cabinet that houses the modules.

The main operational advantages deriving from the combined use of this device can be summarized as follows:

- It is possible to avoid the overheating of fatty tissues
- Maximum heating efficiency
- Accurate localization of the treated area
- Control of heat in depth
- Adequate hyperthermia in depth
- High degree of penetration of the therapeutic effect
- Reduction of complications like erythema and burns
- Low production of electromagnetic noise

3.3 OVERALL VIEW AND GENERAL DESCRIPTION OF THE USER INTERFACE MENU

Figure 3.2 – NOVA device

When turned on, after a few seconds during which the device loads its operating program, a start-up screen is briefly displayed, after which the machine switches to the Options Menu Panel on its own.

Figure 3.3 – Startup Screen

3.3.1 Option Menu (“HOME”) screen

The Options Menu Panel ("HOME") has a menu with five items: four are alternative ways of setting the treatment and one opens the Quick Guide.

The first button, "Selection from Anatomical Model", allows the user, even with little experience, to set a treatment starting from the anatomical district, selectable on the human shape that appears on the screen, and from the diagnosis with the name of the pathology shown in the menus presented alongside the template.

The second button, "Selection by Pathology", allows even the novice with very little experience to set up a treatment "suitable for an average patient"; in principle it may be sufficient to have a diagnosis with the name of the pathology, after which you can go to search for it through the menus offered by this button and the machine will be automatically set.

The third button, "Selection by Structure and Depth", requires a little more experience regarding the use of hyperthermia, but once this is acquired it allows you to adjust the machine parameters for the best, even automatically, for that particular patient and pathology.

The fourth key, "Manual Parameter Selection", allows you to personally adjust the individual machine parameters, therefore it requires the maximum experience: as can be easily deduced, from here you can get the best as well as the worst of the performance, it all depends on the real capabilities of the therapist.

The fifth button, "Quick Guide", allows the user to access a window showing the Control Panel accompanied by explanatory notes that provide the user with the basic information to operate on the equipment.

The following figures show the various panels that appear on the display of the control Panel PC (display + touch-screen) in the various configurations encountered during use.

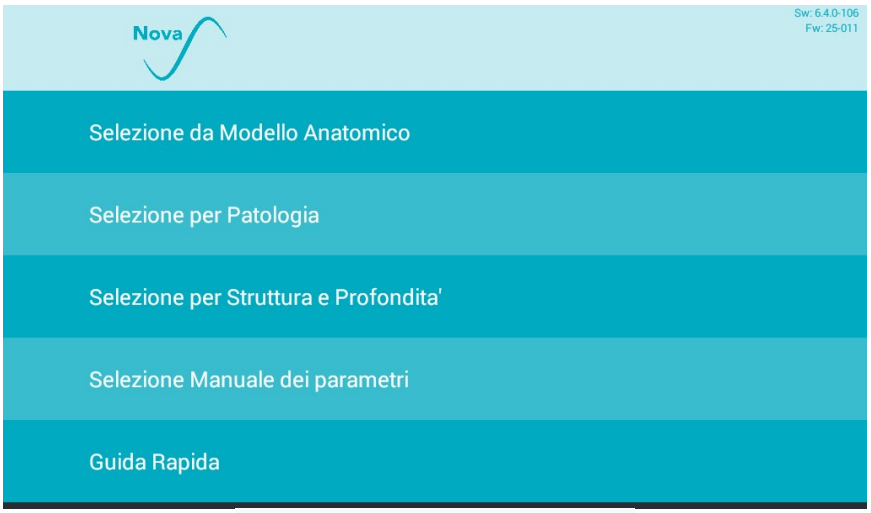


Fig. 3.4 – Option Menu ("HOME")

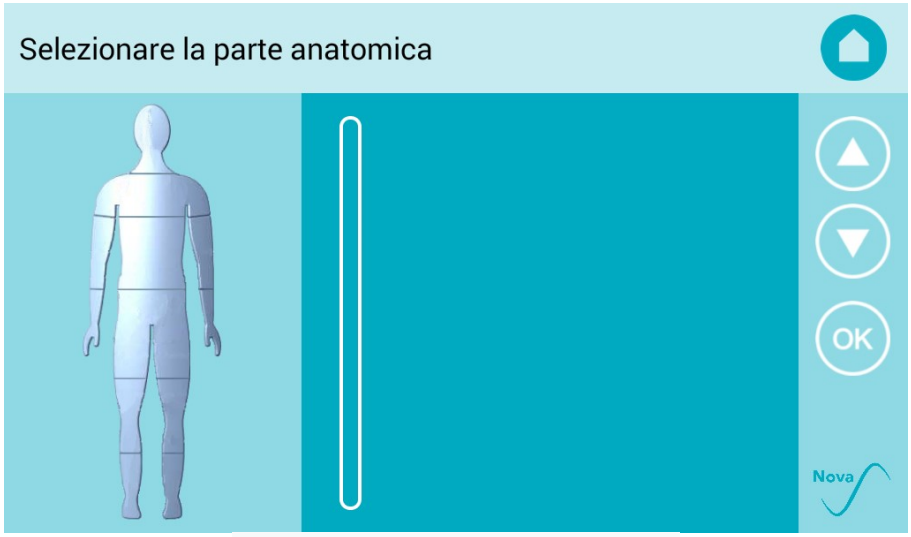


Fig. 3.5 –Select by Pathology, Step 1

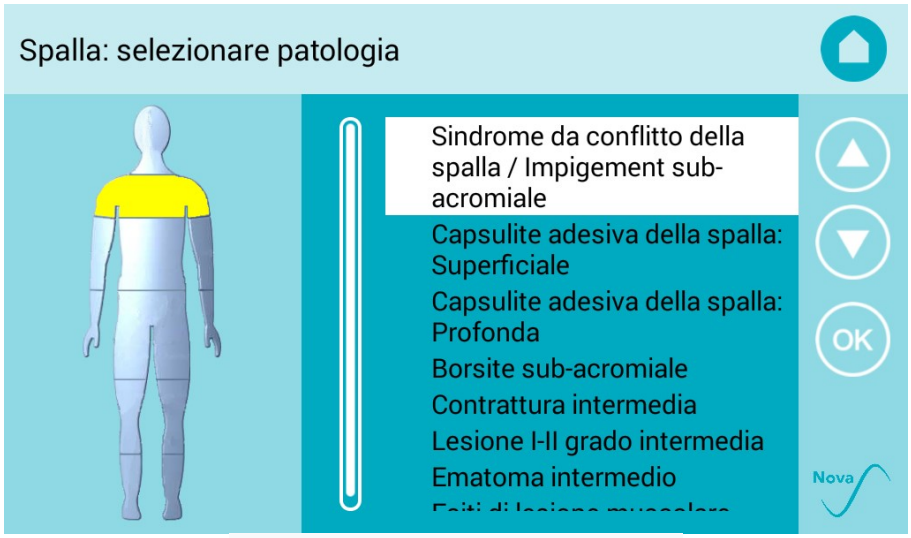


Fig. 3.6 –Select by Pathology, Step 2

Fig. 3.7 – Select by Pathology, Treatment Screen

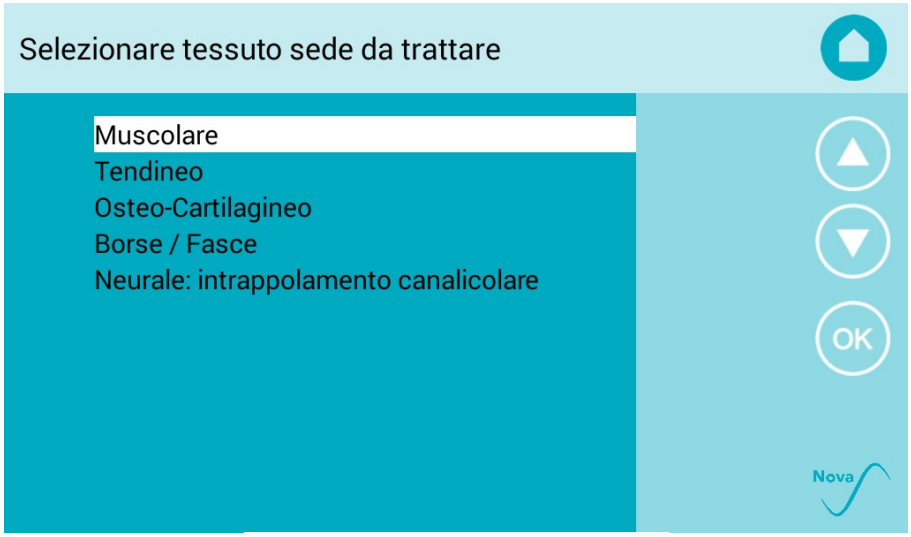


Fig. 3.8 – Pathology Option, Step 1

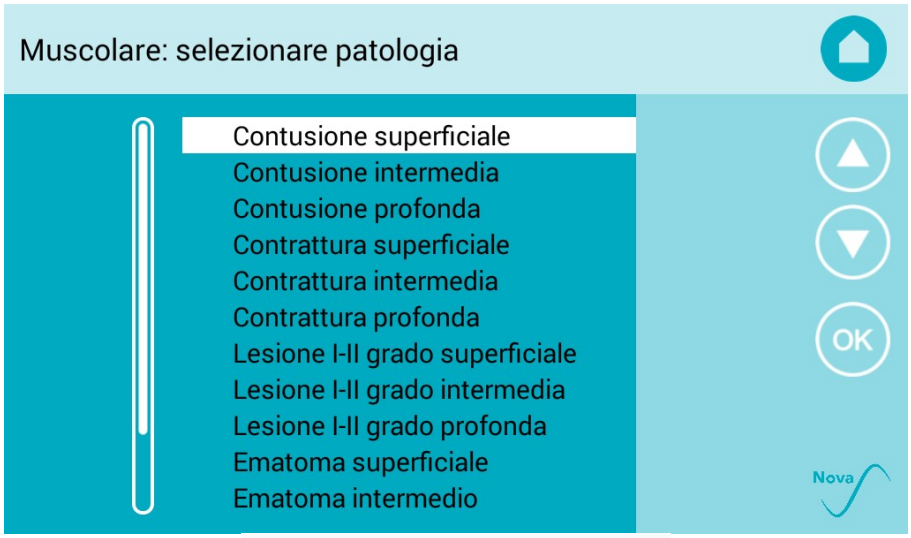


Fig. 3.9 – Pathology Option, Step 2

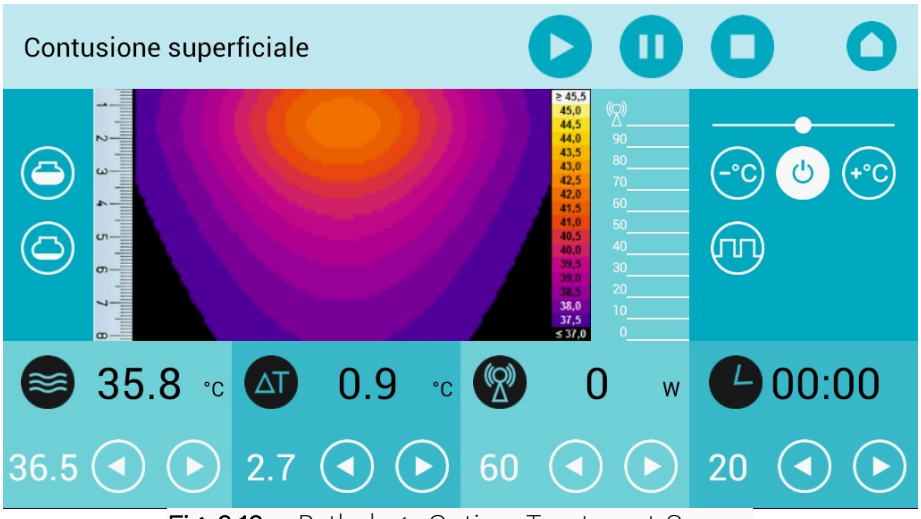


Fig. 3.10 – Pathology Option, Treatment Screen

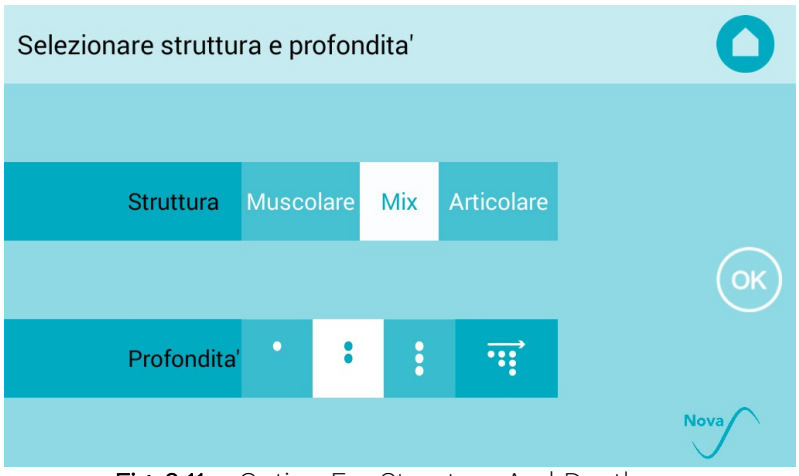


Fig. 3.11 – Option For Structure And Depth

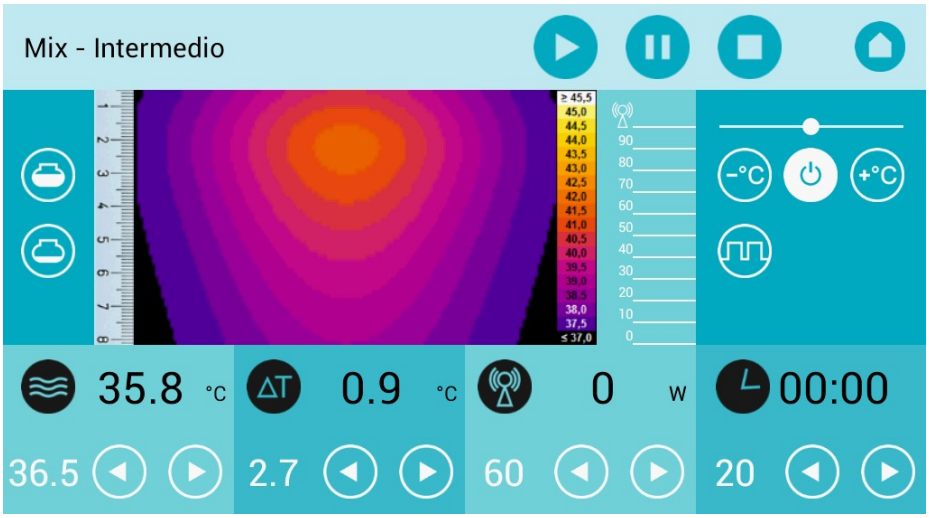


Fig. 3.12 – Option For Structure And Depth, Treatment Screen

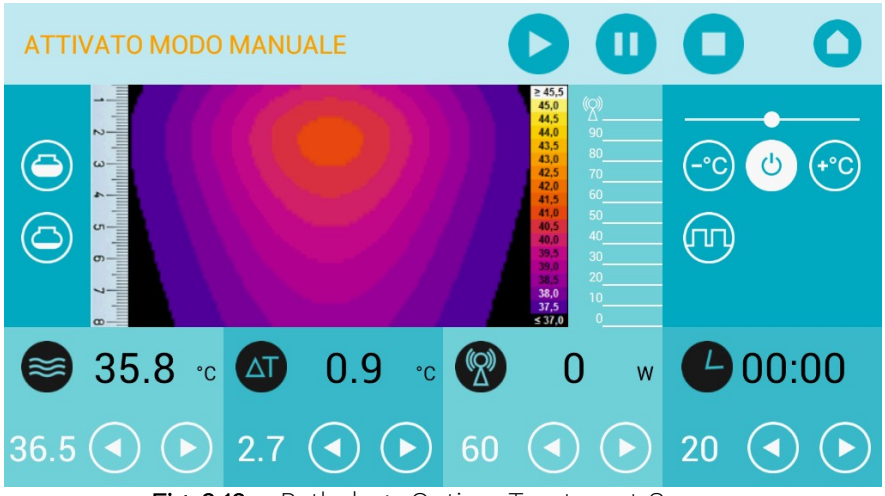
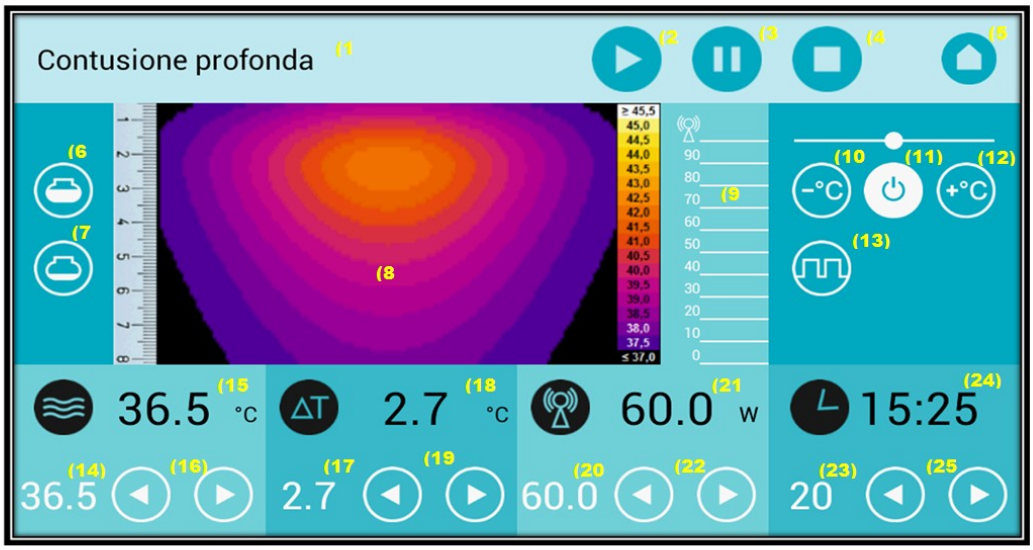


Fig. 3.13 – Pathology Option, Treatment Screen



(1) Tipo di trattamento caricato
(2) START: inizia un trattamento
(3) PAUSA: mette in pausa un trattamento
(4) STOP:
- se il trattamento non è in corso, resetta i parametri di quel trattamento e riaggiorna il grafico;
- se il trattamento è in corso, lo conclude, resetta i parametri di quel trattamento e riaggiorna il grafico
(5) HOME: chiude la scheda del trattamento e ritorna alla schermata principale

Fig. 3.14 – Quick guide

3.4 TECHNICAL SPECIFICATIONS

MICROPROCESSOR CONTROL UNIT

- Session duration control
- Emission power control, both incident and reflected
- Thermostatic fluid temperature control
- Skin/bolus interface temperature control
- Generator efficiency control
- Liquid presence control
- Temperature coherence/limit control
- Thermocouple presence/positioning control

RF GENERATOR

➢ Operating frequency:	433.125 MHz
➢ Maximum power:	100 W (+/- 10%)
➢ Power setting	0 – Pmax
➢ Transmitted power indicator	
➢ Reflected power indicator	

HYPERTHERMIA APPLICATOR

➢ Diameter of radiating section:	100 mm
➢ Coupling with thermo-regulated liquid	
➢ Bolus thickness (if placed vertically on a flat surface)	2.5 cm +/- 0.5cm

SKIN TEMPERATURE CONTROL (HYPERTHERMIA)

➢ T-type thermocouple (copper-constantan)	
➢ DeltaT difference measurement (= Tcutaneous - Tliquid)	
➢ DeltaT setting range	-1 °C ÷ +5°C limit to DeltaT ≤ (42°C - Tliquid)

LIQUID CONDITIONING AND CIRCULATION

➢ NTC, electric resistance at 25° C:	5 kOhm
➢ Adjustable operating range:	35 °C - 42 °C increments 0.1 °C

POWER SUPPLY AND CONSUMPTION

- Mains voltage and frequency: 100-230 V - 50/60 Hz
- Maximum absorbed current: 1.8 A at 230V; 4.0 A at 100V

OVERALL DIMENSIONS AND WEIGHT

- Height (arm excluded) 250 mm
- Height (arm included, at rest) 950 mm
- Width 450 mm
- Depth 660 mm
- Weight (without arm support) 16.6 Kg
- Weight of detachable arm support 2.8 Kg

ENVIRONMENTAL OPERATING CONDITIONS

- Ambient temperature: [+ 20 ÷ + 30] °C
- Relative humidity: [30 ÷ 75] % (non-condensing)
- Atmospheric pressure: [700 ÷ 1060] mbar

4. TREATMENT SETTING AND SESSION SET-UP

ATTENTION: Before starting any treatment, make sure that the safety instructions (Chapter 2) have been complied with, and in particular, make sure there are no contraindications for the patient (paragraph 2.6).

4.1 SWITCHING THE DEVICE ON

Check that the power supply cable is connected to the electrical socket as specified in the instructions and that it is fitted with an appropriate ground connection (as far as it possible to see).

Ensure that the thermocouple surface sensor is correctly applied to the bolus.

Switch NOVA on by using the switch on the rear side of the cabinet.

The management software carries out the functional self-test and does not allow the device to be switched on if the test fails. In this case, it is possible to try switching the device on and off. If the problem cannot be corrected, contact the Technical support.

The device automatically selects the default treatment values, show in the following table, when the treatment is started.

Parameters	Default values
Treatment time	20 min.
Max. power	50 W
Liquid temperature	39 °C
“DeltaT”	1 °C

4.2 WARM-UP/COOLING

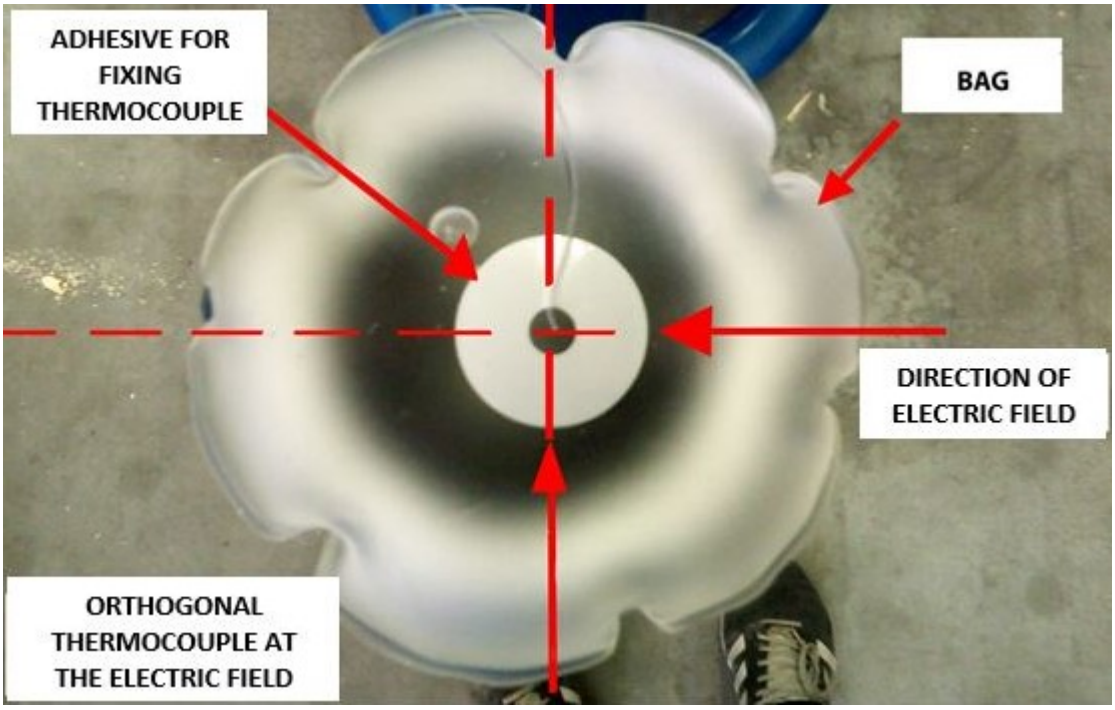
When switched on, the device automatically enables the liquid temperature regulating function, setting the temperature to the default value or to the value selected by the user.
The treatment starts only when the temperature reaches the preset value. When you press START, the device displays a message and issues an acoustic warning.

4.3 PREPARATION OF THE TREATMENT

4.3.1 Position of the surface temperature sensor as compared to the applicator

There are two main points to consider for a correct positioning of the sensor: the centering of the applicator in the radiating opening (area of maximum radiation) and the verticalness of the sensor wires as compared to the electrical field.
In other words it is necessary to maintain the end (sensor) of the wire at the center of the bell mouth opening, while distancing the wire from the center along a straight wire at a right angle from the support arm (on the applicator cover edge there is a mark to show where the wire is expected to slip inside).

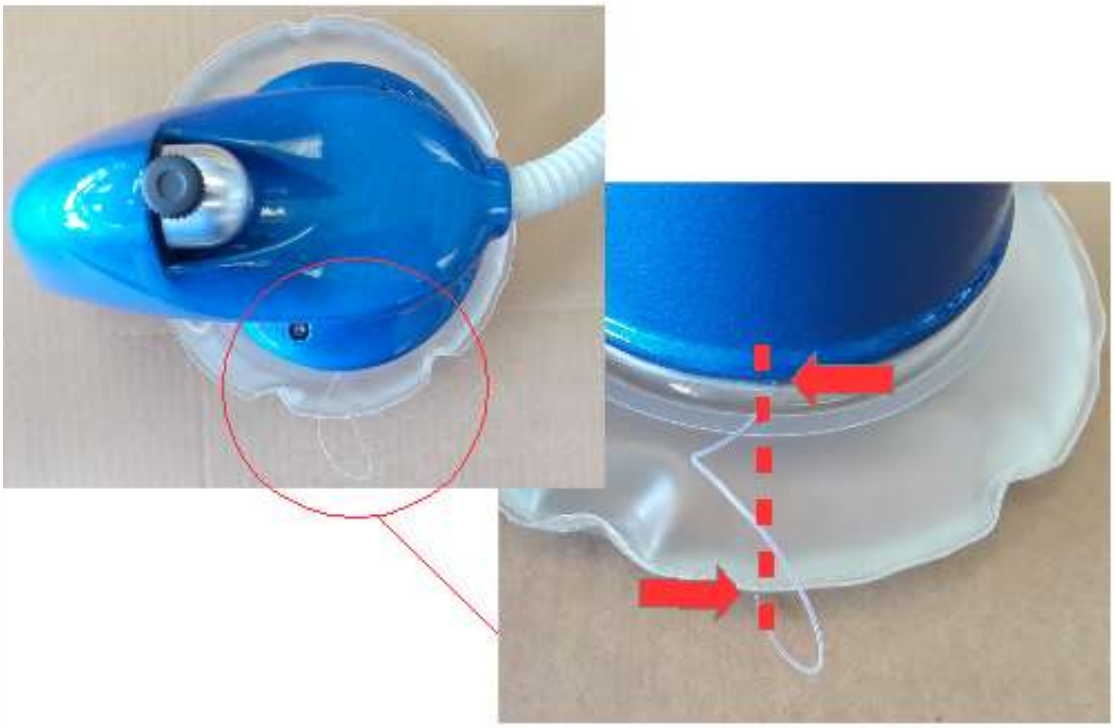
A satisfactory solution is to secure the thermocouple at the center of the lower circular bolus section with thermocouple locking adhesive label, (provided with the device), being careful not to cover the tip (sensing part). It is also important to make sure that the length of the wire under the adhesive tape points towards the arm and the remaining length of the wire is positioned close to the bolus.



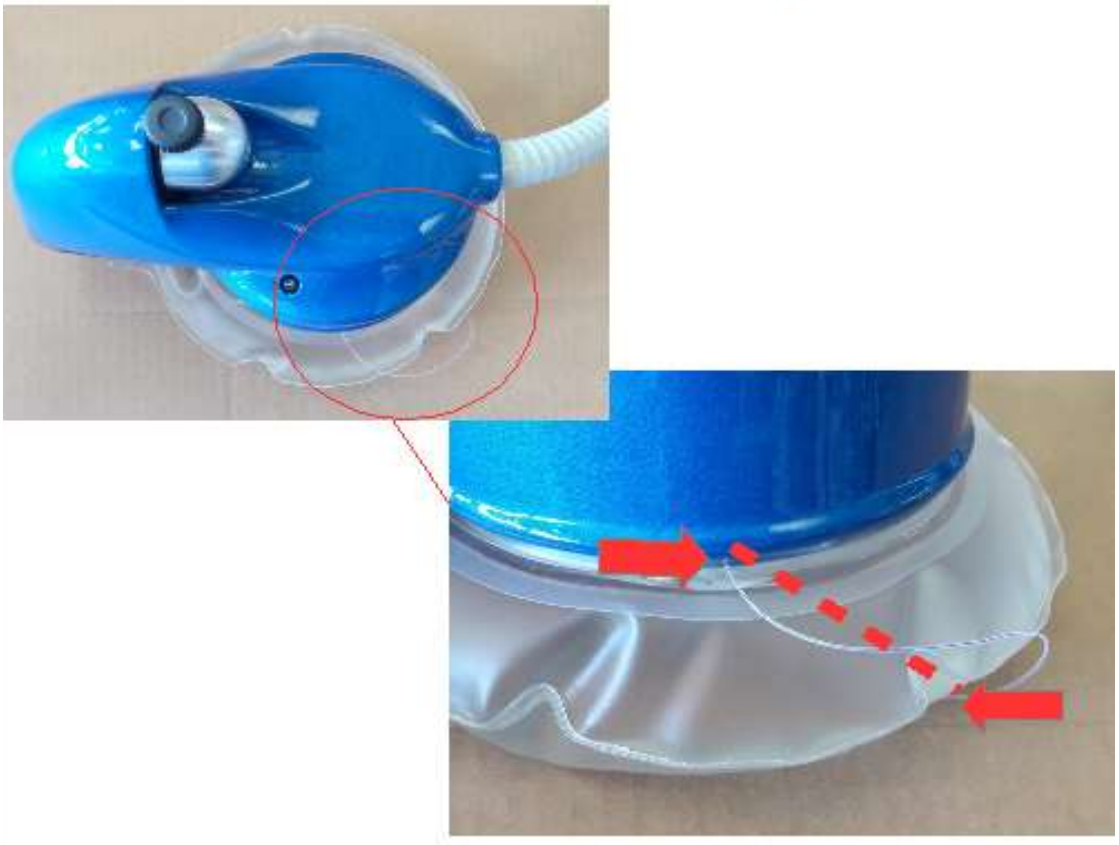
CAUTION

The use of the temperature sensor is mandatory. Using the device without the temperature sensor can cause serious harm to the patient

The adhesive that can be used to fix the thermocouple could be a common medical patch or the one recommended by the manufacturer.



SI



NO

4.3.2 Positioning the patient

It is important to make sure that the patient is comfortably accommodated and relaxed, specifically in relation to the part to be treated.
It is essential to remember that a contracted muscle (that is a muscle that is not relaxed due to the fact that it placed in "difficult" position) hinders the natural circulation of blood, thus influencing the therapy in an uncontrolled manner, while the therapy must rely on the controlled modulation of blood perfusion.
In the specific case of hyperthermia, an uncomfortable position may force the patient to move, which could consequently result in the displacement of the applicator or bolus alone. An excessively narrow bed that forces the patient to hang his arms down, is not suitable for the purpose.
It is finally, but equally important to reduce as far as possible all possible discomfort for the patient as with any other kind of treatment.

4.3.3 Positioning the applicator

A correct centering of the applicator in the area to be treated is essential. This operation is easier if the applicator is used in vertical position. Under these conditions, the bolus, under the effect of gravity, maintains a symmetrical shape that remains well centered as compared to the applicator's mouth. It is therefore preferable for the patient to be positioned with the area to be treated facing upwards.

Asking the patient to lie onto a bed represents the best method to satisfy these conditions.

Appropriate placement of the applicator is simplified thanks to the support arm that can be rotated and extended until it finds the correct bolus centering on the patient and the area to be treated.
At the base of the support arm is the rotary lock knob, loosening or clamping the knob, you can rotate and / or lock the arm in the desired position.
It is also possible to adjust the arm extension with respect to the machine; Loosening or clamping the clamp handle between the two branches of the arm can be extended and locked.
Through the spherical joint, to which the applicator is directly connected, it is also possible to rotate the bolus by placing it in the best way on the area to be treated.

In order to point the applicator correctly, you should in first approximation refer to the law of optics, and view the applicator as a lamp (a desk lamp is the best similarity) which radiates a

“beam of invisible light” that is transmitted to the impinged tissues, and heats them. You should try to place the center of the beam in the center of the area to be treated, where the end of the sensing thermocouple should also be positioned.

For reasons related to electromagnetism:

it is essential that the bolus thickness is placed at a maximum depth of 2 cm in any area, and also that it is never more than 3 cm.

The ideal thickness is 2,5 cm +/- 0.5 cm, but it is however possible to adjust it by placing the applicator vertically along a plan and adjusting the volume with the appropriate controls until the distance between the plan and lower edge of the cover is around 2,5 cm.
In specific cases it is possible to increase or decrease the bolus thickness, taking care that the thickness is between 2 and 3 cm
In the event that through the commands described it is not possible to increase the thickness of the bolus or you notice the presence of air bubbles, it is likely that the liquid level is low. In this case, check it and top up if necessary - see chap. 6.

DON'T DECREASE THE BOLUS LESS THAN 2 CM .
DON'T INCREASE THE BOLUS MORE THAN 3 CM .

BEFORE STARTING THE TREATMENT MAKE SURE THE APPLICATOR IS CORRECTLY POSITIONED. NO TREATMENT MUST BE STARTED WITHOUT THE APPLICATOR HAS BEEN POSITIONED CORRECTLY ON THE PATIENT.

4.3.4 Relationship between the applicator, bolus, thermocouple and area to be treated

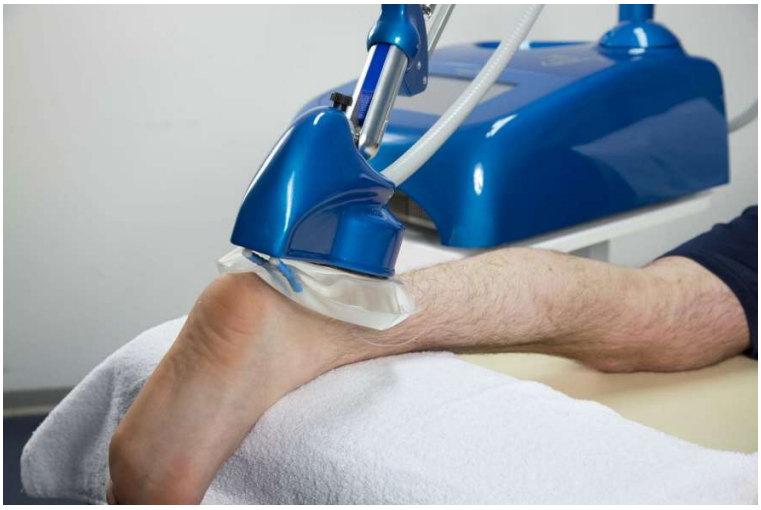
In order to obtain the desired temperature in the tissues, it is essential to create the necessary physical conditions externally so that the internal temperature to be estimated through the use of non-invasive (external) measurements.

These conditions require an effective and reproducible thermal contact between the bolus, the thermocouple and the tissue surface, and for the thermocouple to be positioned in the area of maximum radiation of the applicator and the surface under the area to be treated. It is, therefore, necessary to align the center of the applicator with the center of the bolus, the thermocouple and the center point of the part where you want to induce hyperthermia. You can achieve this more easily if you carefully follow the instructions given above.
Once this is done, the volume of tissue affected by heating is comparable to the size of an egg (chicken's) positioned below the surface of the skin below the applicator. The maximum depth varies according to the treatment parameters, but is limited to 5/6 cm.

4.3.5 Treatment of areas with complex geometry

In most cases the bolus has to be placed on surfaces that are not flat. In some cases it is necessary to carry out the treatment in areas with multiple bends, such as joints.

This, together with the fact that the dielectric properties of the liquid (bolus) are not the same as those of the body tissues (that are not homogenous) may cause a partial deformation of the electromagnetic field and consequently affect the distribution of the temperature in the tissues as compared to the ideal case consisting in a flat surface and a homogenous body.
An impairment of electromagnetic matching may also occur. If the mismatch is significant, the device will signal this condition before the treatment is started.
If necessary, it is possible to eliminate or reduce these problems by adjusting the volume of the bolus while preparing the device for the treatment or during the treatment.



4.4 TREATMENT PARAMETER SETUP: MANUAL MODE

For a clear description, the first treatment setting mode that should be considered is the Manual Mode.

Operations begin from the Option Menu Screen ("HOME").
Clicking on the “Manual Selection of Treatment Parameters” we enter the Manual Mode Setup screen (Fig.4.1).
(Machine parameters are left in the stand-by / default settings).

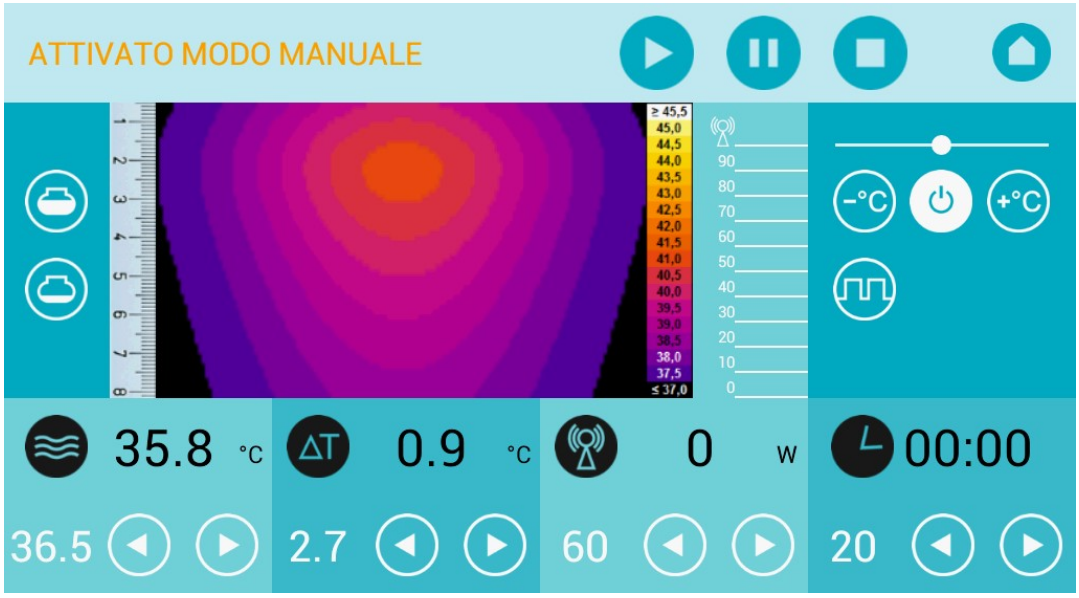


Fig.4.1 – Display when the Manual Mode is active, before the start of the treatment itself

The display is divided in several areas comprising one or more buttons.
In the upper right corner you can see the HOME key which allows returning the machine state to stand-by/ default, and to its “Option Menu” screen. This key has always the same function in all the screens where it is present.
On the left there are the three main operation buttons with the usual symbols for **“Start”, “Pause”, “Stop”**, that are used to start, temporarily suspend or terminate the treatment session.
The **“Start”** button lets the treatment begin; in other words, the control board, on receipt of the “start” command, verifies that all preconditions and safety checks are satisfied (in particular, it checks the water temperature; we'll see later the other checks) and if everything is as expected, it starts the timer and adjusts continuously the radio-frequency power emission to reach and, later on, maintain the temperature differential (deltaT); at the same time, the water temperature is monitored so that it remains at the pre-set value. Pressing again the “Start” button when the session is ongoing will have no effect.
The **“Pause”** button temporarily suspends the session, that is, it stops the timer and halts all radiofrequency energy emissions, while keeping the remaining functions active. This is mainly used to adjust the patient's position or tune the treatment parameters if they are deemed to be less than optimal, or to effect some therapy (e.g. mobilisation) on the patient. Hitting the “Pause” button again when in “Pause” mode has no effect. To resume the treatment, the operator must press the “Start” button.

The **"Stop"** button halts the treatment and brings the device back to the state described at the beginning of this paragraph, displaying again the Treatment Parameter Setup screen. The parameters being displayed are reset to their defaults values, and all changes made are lost). Hitting again the "Stop" button when the machine is in this stopped state has no effect. The same applies if the treatment has not yet started.

Also on the left, above, there is an informational message "Manual Model Active". This same area is used in the other screens as a reminder of the device's operational status.

Below, in the large rectangular window on the left, are some useful tips, for example:

"The patient must be in a comfortable, relaxed position, with the surface being treated facing as close as possible to upwards, to achieve the best possible positioning for the applicator. During the treatment, verify that the positioning is still optimal."

All the lower half of the display is taken by the keyboard with all the commands in detail. This is the core of the Manual Mode. Through this keyboard, the operator can set all parameters to any admissible value, according to the allowed ranges for each; the control board will nonetheless perform a consistency check based on its internal limiting parameters (these shall be described later, and are stored in the control board itself).
The four command windows in the lower screen area allow configuring: the water temperature (i.e., that of the bolus), the temperature differential ("DeltaT"), that is, the temperature difference between what is measured by a contact sensor between the bolus and the skin and the temperature of the bolus itself, the maximum radio-frequency power allowed for the session, and the session duration.
For each configurable parameter there are two buttons, one increasing and the other decreasing the value by a fixed, discrete amount, as defined hereafter.
A short pressure of the key changes the value by one step (i.e., the rightmost digit on the parameter window changes by one integer unit). By keeping the key pressed longer than 0.3 s, the autorepeat function kicks in and the value is changed at a higher speed (one step every 0.1 s).
On the left, near each pair of keys, are reported: below, the values of the parameters being set (which vary according to the setting keys), and above, in a larger font, the current values of the same quantities, as measured/detected by the device. In this Treatment Display we will then be able to see the default values and the current values (zero for time and RF power, and the current temperatures and deltaT measured by the thermal sensors).

The radio-frequency power setup is done in increments of 1 W, and the reading has also a precision of 1 W.
The water temperature setting and measurement are both displayed with a precision of 0.1 °C.
The DeltaT setup, and again its measurement, are both displayed with a precision of 0,1°C.
The time setting is done in steps of 1 minute, and the corresponding display changes in steps of one whole minute. The time measurement on the other hand is given with minutes and seconds.

Each parameter can only be set in a predetermined range of values; moreover, the device continuously performs the "consistency check" both between the parameters that you try to set and in relation to the machine status, and consequently prevents certain actions in order to reduce the possibility of causing thermal damage to the patient. It should be borne in mind, however, that the great variety of treatments that can be performed (different pathologies, different state of the problem, different patients) necessarily allows you to set values which in some cases can be harmful. This can and should only be controlled by the operator. For this the Manual Mode is dedicated to the most expert.

Adjustable ranges

- RF power: It can be set from 0 to 100 W.
- Water temperature Tw: It can be set from 35 to 42 ° C.
- DeltaT temperature: It can be set from –1 to + 5 ° C.
- Time: It can be set from 1 to 60 minutes. Furthermore, once the treatment has started, it can be extended up to a maximum of 60 minutes or shortened to the time already elapsed.

Coherence of parameters

- A temperature pair cannot be set such that the sum Tw + DeltaT (considered as skin temperature Tsk) is greater than 42 ° C
- The treatment does not start if the water is at a temperature outside the range of - 2 ÷ + 2 ° C around the set value. In this case, a short acoustic signal (beep) is also emitted every time the operator tries to start the treatment, to draw attention. A visual signal / message is also turned on.

- The treatment does not start if the measurement of the skin temperature Tsk (= Tacqua + DeltaT) has a value lower than 33 ° C: in fact this means that the sensor is not positioned between the bolus and the skin - and therefore must be placed properly -, or that the skin is temporarily very cold - and in this case just wait a few tens of seconds with the bolus resting on the part to be treated to warm the surface -, or that the water is very cold (in this case also the previous point blocks the RF). In this case (Tsk <33 ° C) a short acoustic signal (beep) is also emitted every time the operator tries to start the treatment, to draw attention. A visual signal / message is also turned on.

- The treatment does not start if the measurement of the DeltaT is excessively low or high (extremes of the dynamics of the thermometric channel): it means that the sensor is broken or not inserted in the connector.

- If during the treatment the water is at a temperature outside the range of ± 2 ° C around the set value, the RF emission is stopped. In fact, this means that either there is a fault or the operator is recklessly tweaking the water setting. In this case, a characteristic acoustic signal is also emitted: two beeps in rapid sequence, then 3 seconds of silence, and so on cyclically until the problem is resolved. A visual signal / message is also turned on. The timer continues to walk. If the operator tries to restart the treatment via RF ON, it is prevented and a short beep and a visual signal / message are emitted as when similar conditions occur at the beginning of the treatment.

- If during the treatment the measurement of the skin temperature Tsk (Tw + DeltaT) reaches a value lower than 33 ° C, the RF emission is interrupted: in fact this means that the sensor is not positioned between the bolus and the skin (or that the water is very cold, but in this case the previous point also blocks the RF). In this case, a characteristic acoustic signal is also emitted: two beeps in rapid sequence, then 3 seconds of silence, and so on cyclically until the problem is resolved. A visual signal / message is also turned on. The timer continues to walk. If the operator tries to restart the treatment via RF ON, this is prevented and a short beep and a visual signal / message are emitted as when similar conditions occur at the beginning of the treatment.

- The treatment is interrupted if the measurement of the surface T is excessively low or high (extremes of the dynamics of the thermometric channel): it means that the sensor is broken or not inserted in the connector.

Logically the set of four set values is updated as you act on the keyboard.

On the left, above, there are two keys to vary the volume of the water cushion (bolus). Usually, once set, this volume needs not further adjustments for quite some time.
The upper key controls the increase of the bolus volume, while the lower key controls its decrease.
Since both increase and decrease of the bolus volume require some time, once a button is pressed the function remains active for 30 seconds even if the button is released. By pressing the same button, or the other one, again, while the volume is changing, the function is immediately interrupted. This means that to invert the operation within the 30 seconds it is necessary to press the other button twice: once to stop, the second time to start the operation in the opposite direction.

During the active bolus volume alteration stage, the device emits a loud, distinctive warning beep. Hitting the Bolus volume keys has no effect either on the setting or duration of the treatment; the control board effects the necessary changes automatically and independently.

On the far right, the “Power Intensity” key area allows varying the temperature distribution in steps of approximately half a degree. The first three keys are labeled:

- “+°C,
- Norm,
- “-°C”.

By default, the “Norm” key is highlighted, indicating that no alteration has been entered. The “+ °C” (warmer) and “- °C” (cooler) cause an incremental alteration in the temperature, within the range allowed by the machine. As soon as the default setting is changed, that of the two keys that has been pressed is highlighted instead, to indicate that the treatment temperature has been modified. By pressing the “Norm” key even once, the reference temperature is immediately reset to the value it had before any alteration began.

How the machine parameters are modified in response to an increase or decrease in the emissive intensity will be explained in a later chapter on the connection between treatment types and machine setup,

Above these three keys there is a slider with a pointer which by default is set dead center (“Norm”), moving right or left at each pressure on either the “Warmer” or “Cooler” control key.

Important Notice: the concept of “higher” or “lower” intensity makes only sense in reference to some preexisting parameter set. If, after changing the intensity setup, the operator were to press any of the six RF power or temperature control buttons, the new parameter set which gets thus entered becomes the new reference point and is accepted as manually entered, while the “Intensity” area is reset to “Norm”. At this point it is of course possible to increase or decrease the intensity in relation to the new baseline using the “+ °C” and “- °C” buttons.
In summary, to keep track of the actual absolute intensity, it is necessary to manipulate the Intensity control area *last*. This holds both for the setup and the treatment phase.

In the same “Intensity” area, under the three keys described above, there is the power modulation button. This function involves normal heating for a period of three minutes,

followed by one-minute pause, after which the cycle begins anew, repeating the whole duration of the treatment session.

The stand-by / default status involves a parameter set corresponding to an “intermediate” treatment. These values are those for “Mixed Structure, Intermediate Depth, Normal Intensity”, that we will next see in the “Structure and Depth Treatment Setup” paragraph.

It must be remembered that even in standby position, the device is still either bringing the water to the pre-set temperature, or actively keeping the temperature at the pre-set value if it has already been reached. This is necessary because the typical time to reach thermal stability is around 20 minutes from cold start; therefore, the device is usually powered on beforehand, so that it will be ready when needed.

In the middle right of the display there is a vertical window and a graduated scale with a 0 to 100 range, in increments of 10 units. Its total length represents the maximum RF power allowed in the selected treatment (PmaxRF).

Once the treatment starts, this scale will display the percentage of emitted radio-frequency power relative to PmaxRF, and of this power, how much gets reflected back into the generator and how much enters the tissues (the next display will explain this in more detail).

Setting up the treatment as described above takes perhaps the most time; next, it will be described how to “cut corners”, losing some optimizations and keeping the device's benefits to a bare minimum. It is possible to use the pre-set defaults and start the treatment straight away, not taking into account how well it fits with the actual patient or pathology being treated.

4.4.1 Treatment start-up and Performing the session (Manual Mode)

Once verified that the liquid temperature has stabilized on the desired level, the operator can hit Start and begin the treatment (Manual Mode, Treatment Started screen, Fig.4.2).

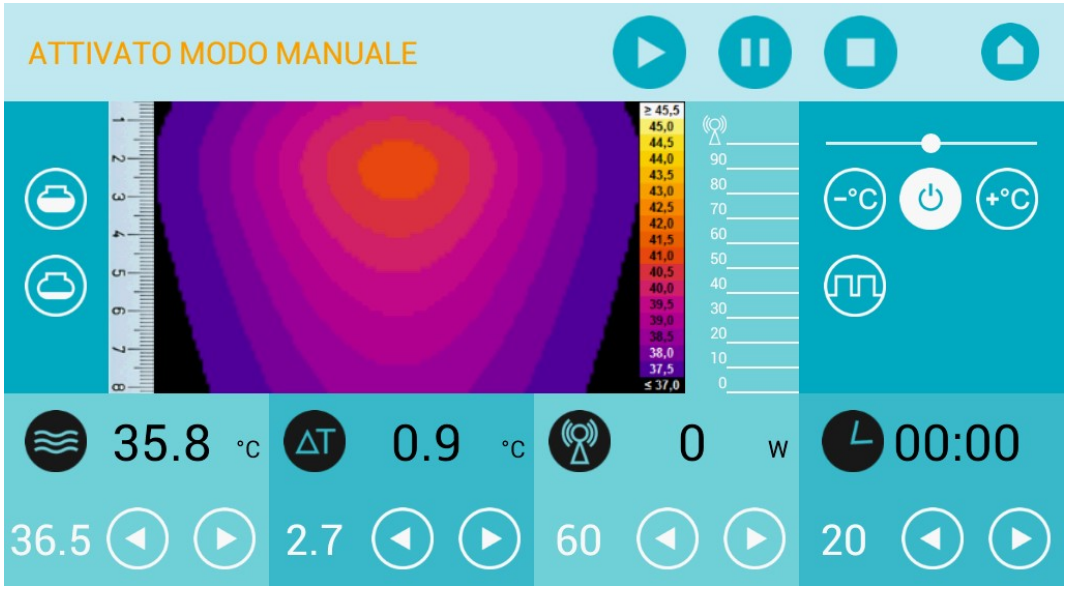


Fig.4.2 – Display with Manual Mode, Treatment Started with the “Start” button

The display is almost identical to the one before, with the following differences.

All commands are active except the “Home” button, that will remain deactivated until the treatment either stops by itself or is interrupted with the “Stop” button.

The treatment can therefore be adjusted at any time, if needed. The “Pause” key will suspend both the radiofrequency emission and the timer, thus allowing the operator to safely perform any adjustment (on the patient as well) and fine tuning and starting the treatment again with “Start”.

It is in this moment (with the device in “Pause” mode) that intensity adjustment with the keys in the “Intensity” area can be most useful. Indeed, the adjustment function has not been designed so much for the “Setup” stage as for the treatment stage, to correct the intensity while keeping the same treatment parameters, for example if the patient feels discomfort due to excessive heat.

While the treatment goes on, the radiofrequency power is emitted and on the vertical bar this is represented by a stacked histogram: the vertical bar is divided in two adjacent segments of different colors, the lower one representing the fraction of the power reflected back into the generator, the top one the power entering the patient's tissues. The first bar is colored orange as a warning, while the top bar is a reassuring green.
The large free rectangle displays the temperature distribution within the tissues as generated by the simulator.

It must be noted that in this case, i.e., when starting from the Manual Treatment Parameters Setup, the simulator uses a default tissue structure model, and this setting cannot be changed. If the operator wants a different tissue structure model to be employed, he or she must start from “Structure and Depth Treatment Parameters Setup”, and *then* enter Manual Mode with the quick switch method that will be illustrated in the next chapter; or accept the structure model that will be automatically assigned when starting from “Treatment Selection by Pathology”.

The treatment can be interrupted in any moment by pressing “Stop”. In this case the device goes back to the starting treatment screen, with all parameters reset to the default. All changes made by the operator are lost, the water temperature setting is reset to the default and the device starts adjusting the water temperature to match the new value. Pressing “Stop” repeatedly has no effect, since the first pressure already sets the device in the default stopped mode.

At this point, if the operator wants to go back to the “Option Menu Screen” and related parameters, it is necessary to hit the “Home” key.

In normal circumstances, the treatment ends when the allotted time expires. Now also the Treatment Setup screen is displayed and the device enters the stopped state, with all parameters reset to default and user changes lost, including water temperature setting, but now the device starts emitting warning noises and requires the operator to terminate the session by pressing the “Stop” key.

At this point, if the operator wants to go back to the “Option Menu Screen” and related parameters, it is necessary to hit the “Home” key.

4.5 TREATMENT PARAMETERS SETUP: STRUCTURE AND DEPTH MODE

The second treatment parameter setup method that it is convenient to consider now is the one "By Structure and Depth".

Starting again from the Home ("Option Menu") screen, the operator selects the "Structure and Depth Treatment Setup".

The device displays the "Structure and Depth Treatment Setup" screen show in Fig. 4.3.

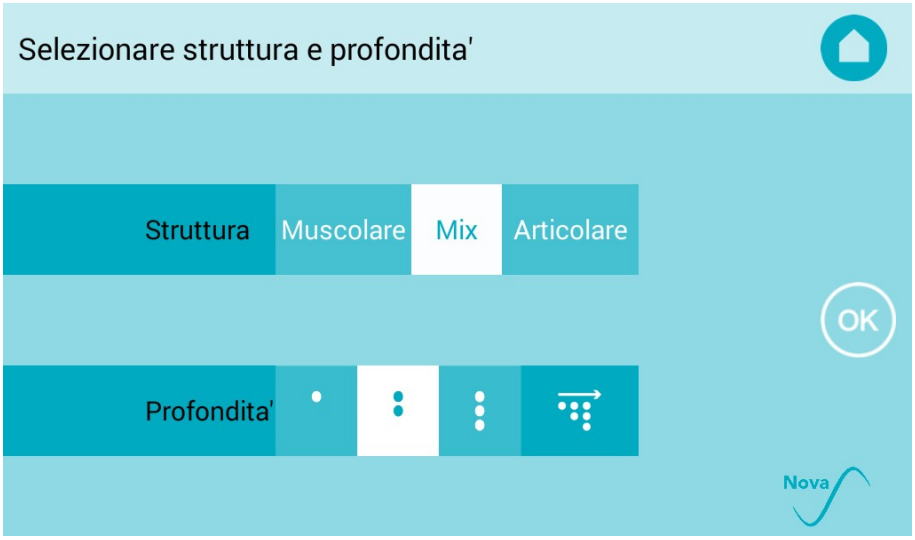


Fig. 4.3 – Treatment Setup by Structure and Depth

To go back to the Options Menu screen, the operator hits the "Home" key.

Below it, there is a key area dedicated to the treatment selection, which is done by selecting the structure of the area to be treated and the depth that it is necessary to reach.

There are three tissue structure types based on two different tissues: "All Muscular", "All Articular" and "Muscoloarticular mix". This means that underneath the skin and the fatty layer where present, we may find muscle tissue (e.g. in the thigh), muscle joined to an articular joint or a tendon (as happens in the shoulder), or just the joint itself (e.g. in the knee). These three types are mapped to the keys "Muscular", "Mix" and "Articular".

There are then three depth levels, "Surface", "Intermediate" and "Deep", determining where the largest fraction of the treatment power is to be focused, depending on both the specific pathology and the body proportions of a given patient; these three levels are selected with the depth keys, labeled with one, two or three circles.

These 3 + 3 keys yield nine possible different treatments (i.e. 9 different sets of the four machine parameters), covering practically all possible needs.

In the same area, the "Dynamic" key instructs the machine to perform a variable depth treatment cycling between the three available depth settings, as will be described later.

In the initial machine state for the "Structure and Depth Parameter Setting" screen, the device is set for "Mixed" structure at "Intermediate" depth (two circles key). On a side note, currently this is also the same parameter set for the stand-by/default state of the Options Menu ("Home").

The three keys "Muscular", "Articular" and "Mix" are mutually exclusive; the same holds for the four keys controlling depth.

This means that however the tissue structure and the treatment depth are chosen, two keys and only two keys will be active.

If the “Dynamic” setting has been selected, the device will perform 6 minutes of surface treatment, followed by 7 minutes at intermediate depth, followed by 7 minutes at full depth, while keeping the same tissue structure setting. Additionally, during the last minute of surface treatment, the water temperature will be set to the value for the Intermediate depth, and during the last two minutes of Intermediate depth treatment the temperature will be set to the value required for the Deep treatment.

Whichever pair of keys has been selected, the choice needs to be confirmed by hitting the “OK” button.

Once done this, the device displays the “Treatment in Progress” screen (Fig. 4.4). For an overview of this screen, check out “Treatment Progress Screen: Manual Mode” (sections 4.4 e 4.5).

Below, the differences with the Manual Model version of this screen will be describe.

The information at the top will be consistent with the new situation. For example if the default parameters have been left untouched, the operator will see a specification of ““MIX – Intermediate Depth”, and the four numbers of the bottom line will have remained the same from the stand-by / default values.

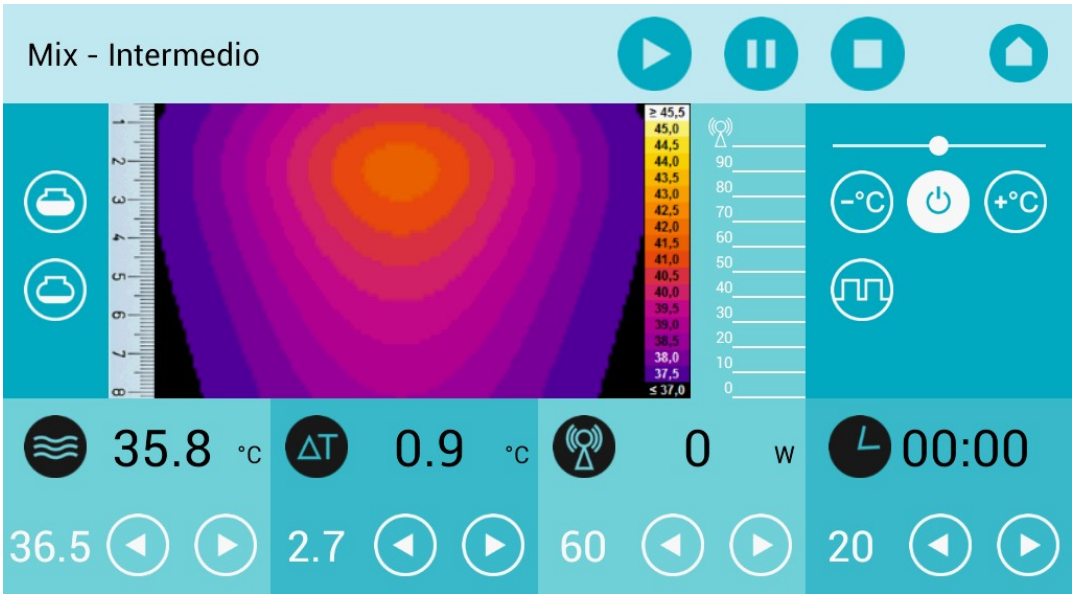


Fig. 4.4 – Treatment setup example with “MIX” structure and “Intermediate” depth.

If a different structure and/or depth has been selected, the four numbers in the bottom row will have changed to the appropriate values for the chosen treatment.

On a side note, the device will immediately start adjusting the water temperature. In general, every time that the water temperature setting is changed in any way, the device immediately starts adjusting the water temperature towards the new value.

As for the “Manual Mode”, the large rectangular window on the left will show some tips.

Setting up the treatment as described above is perhaps the faster way, since it involves the minor number of key clicks.

The machine is ready to start the treatment by pressing the “Start” keys; once the preflight checks have been performed and passed, the treatment can begin.

Before pressing "Start" let us see what happens if some other key is pressed.

- The "Bolus" buttons can be freely used.

- The "Intensity" area buttons can also be used, even if this would be better done once the treatment has begun, and not before, except for the "Modulation" option.

- The two timer buttons are also working; even if a markedly shorter or longer treatment makes little sense, this possibility is available to the operator. Using these keys sets up different session lengths; the device will take in the last key pressed.

ON THE OTHER HAND the six keys governing radiofrequency power, water temperature and DeltaT are the most sensitive, since hitting any one of them even once will mean exiting from the bounds of a "pre-set" treatment (such as the ones described in the current section) and enter the Manual Mode, with all the detailed commands unlocked and available.

What does happen:

a) The informational label at the top changes to a "MANUAL MODE ACTIVATED" in a flashy color such as orange. It blinks to attract attention, then steadies and indicates that we are indeed in manual mode. To go back to the "Structure and Depth mode" simply stop the treatment by pressing "STOP" buttons.

b) As explained in the "Manual Mode" section, the current settings are taken as the new "Normal" reference, and the Intensity gauge is returned to "Normal" position, without changing the tuning parameters, that have been manually entered by the operator.

c) The setup parameters remain the same as before entering manual mode, with the exception of those that have been modified in the above mentioned group of six keys, that will assume the new value entered by the operator.

All this remains true even after the "Start" button has been pressed, i.e. with the treatment under way.

But supposing that no manual change has been entered, we would be in the Treatment Ready screen of Fig. 4.8 (MIX – Intermediate Depth) ready to start the treatment.

4.5.1 Treatment start-up and Performing the session (structure and depth mode)

Once pressed the “Start” button the screen shows:

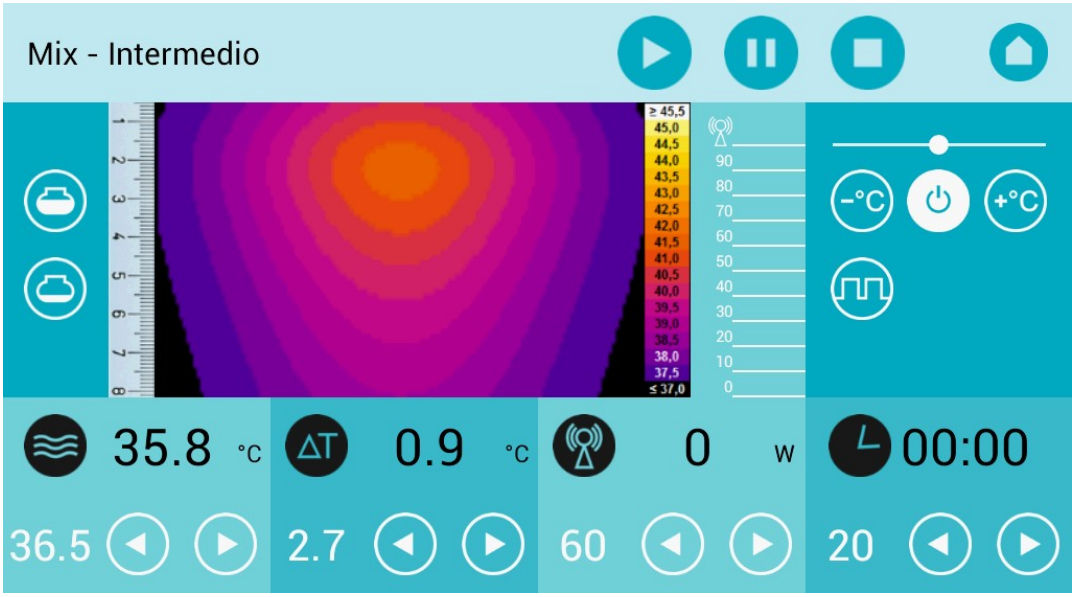


Fig. 4.5 – Treatment started in “Selection by Structure and Depth” mode.

The information label on top is a reminder of the chosen treatment type.

Otherwise, the screen is identical to the corresponding one in “Manual Mode” except for the different values of the setup parameters. Here, as it happened before hitting “Start”, any action on the six critical keys at the bottom will enter Manual Mode and change on-screen indications accordingly.

The commands behave in the same way than in Manual Mode, and in particular, the treatment can be immediately terminated by hitting “Stop”.

Unless stopped manually, the session will continue until the pre-set time expires.

At that point, to go back to the default, i.e. to the “Option Menu” (“Home”) screen, it is necessary to hit the “Home” button.

4.6 TREATMENT PARAMETERS SETUP: PATHOLOGY MODE

Starting again from the Home (“Option Menu”) screen, the operator selects the “Pathology Treatment Setup”.

This enters the “Select by Pathology” screen, Step 1 (Fig. 4.6). Keeping in mind the tissue type with the greatest amount of damage needing treatment, and/or the desired effect, the operator uses the up and down arrows to choose among the nine offered options (this has nothing to do with the nine possible treatments available in the previous mode, the number nine being coincidental).

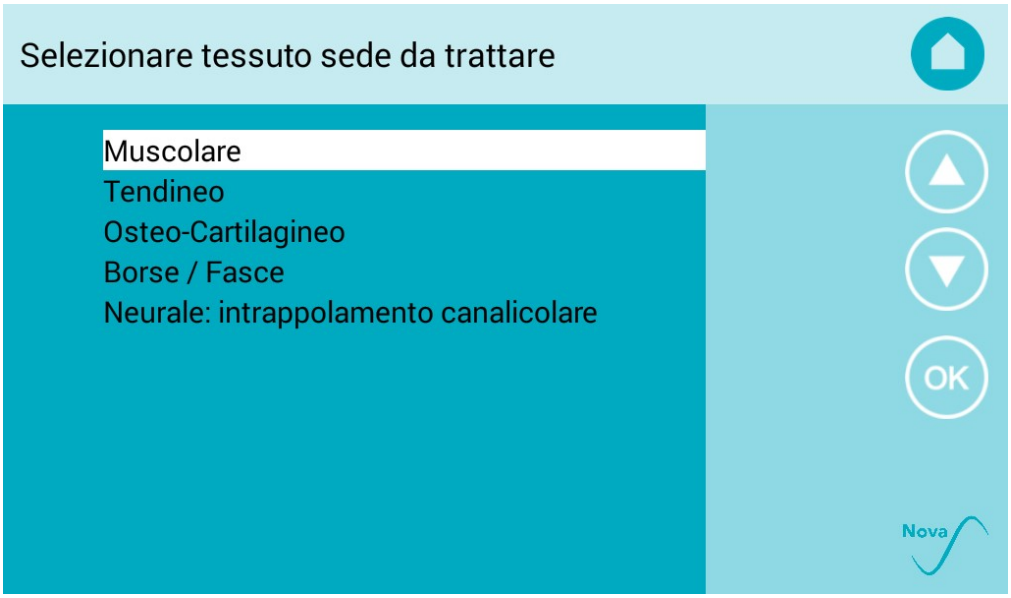


Fig.4.6 – Display ready to select the tissue to be treated

Confirming the choice with the "OK" key advances to the "Selection by Pathology" screen, step 2 (Fig. 4.7) corresponding to the choice made.

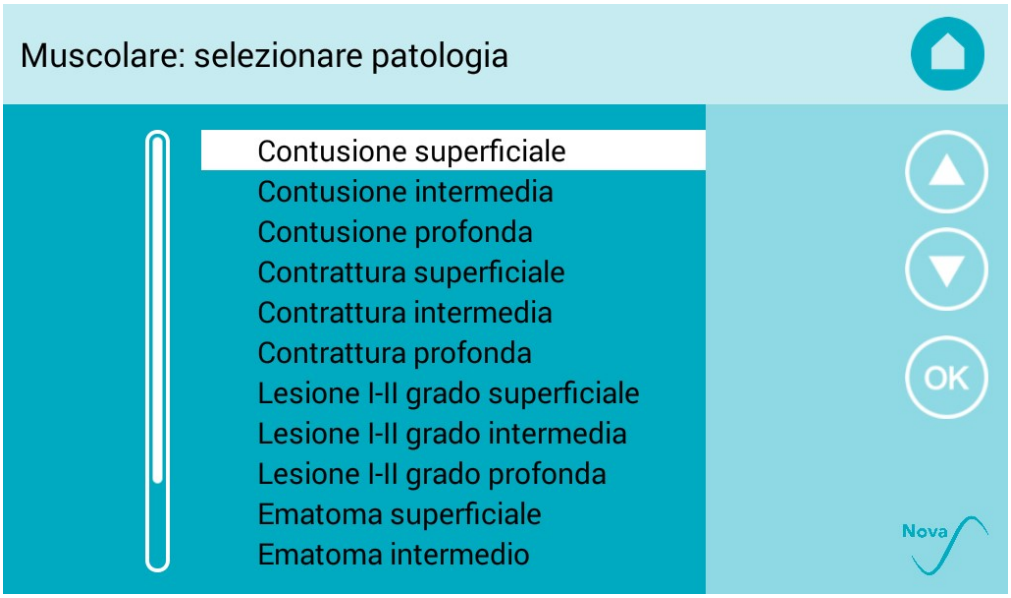


Fig. 4.7 – Display ready to select a pathology

In the same way, the operator chooses one of the proposed options.

Confirming again with "OK" enters the Treatment screen (Fig. 4.8). For an overview, please refer to "Treatment Screen" in "Manual Mode" (sections 4.4 and 4.5).

We will now see the differences with the above mentioned "Manual Mode" Treatment screen.

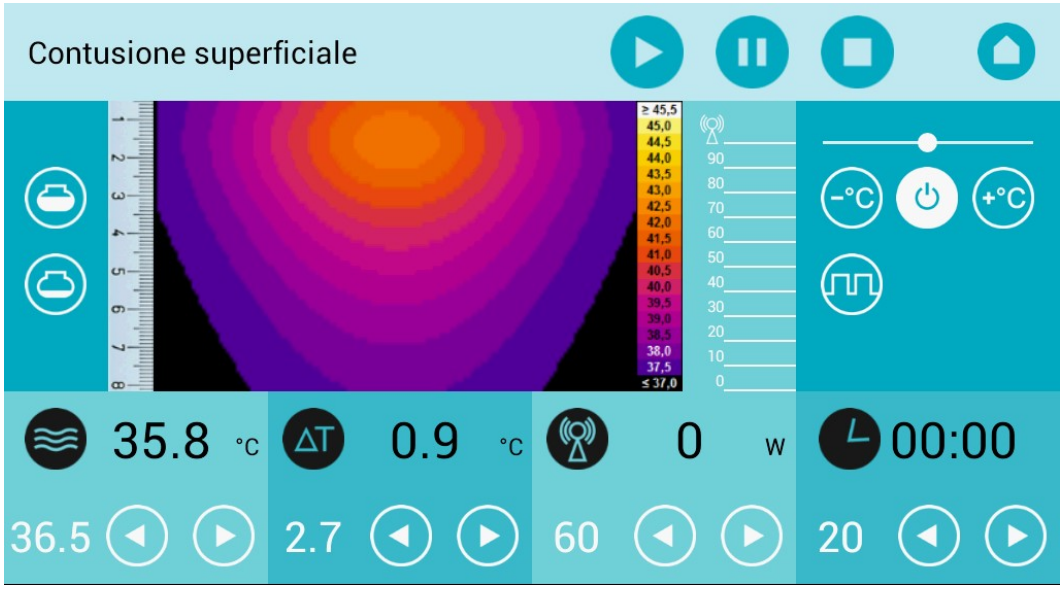


Fig. 4.8 – Display ready to begin the treatment

The informational label at the top will be consistent with the new situation: for example if "Muscular" had been chosen in Step 1 and "Superficial I-II degree lesion" had been chosen in Step 2, in the Treatment Screen the informational label at the top would refer to these options, and the four numbers in the bottom row will report the values associated with that specific treatment.

On a side note, the device will immediately start adjusting the water temperature. In general, every time that the water temperature setting is changed in any way, the device immediately starts adjusting the water temperature towards the new value.

Setting up the treatment in this way is quite fast, since only few key presses are required.

The machine is ready to start the treatment by pressing the "Start" keys; once the preflight checks have been performed and passed, the treatment can begin.

But before pressing "Start", as with "Structure and Depth" mode, let us see what happens if some other buttons is pressed.

- The "Bolus" buttons can be freely used.

- The "Intensity" area buttons can also be used, even if this would be better done once the treatment has begun, and not before, except for the "Modulation" option.

- The two timer buttons are also working; even if a markedly shorter or longer treatment makes little sense, this possibility is available to the operator. Using these keys sets up different session lengths; the device will take in the last key pressed.

ON THE OTHER HAND the six keys governing radiofrequency power, water temperature and deltaT are the most sensitive, since hitting any one of them even once will mean exiting from the bounds of a "pre-set" treatment (such as the ones described in the current section and selected by pathology) and enter the Manual Mode, with all the detailed commands unlocked and available.

What does happen:

a) The informational label at the top changes to a "MANUAL MODE ACTIVATED" in a flashy color such as orange. It blinks to attract attention, then steadies and indicates that we are indeed in manual mode. To go back to the "Structure and Depth mode" simply stop the treatment by pressing "STOP" buttons.

b) As explained in the “Manual Mode” section, the current settings are taken as the new “Normal” reference, and the Intensity gauge is returned to “Normal” position, without changing the tuning parameters, that have been manually entered by the operator.

c) The setup parameters remain the same as before entering manual mode, with the exception of those that have been modified in the above mentioned group of six keys, that will assume the new value entered by the operator.

All this remains true even after the “Start” button has been pressed, i.e. with the treatment under way.

Supposing that “Muscular” was chosen in Step 1 and “Superficial I-II degree lesion” in Step 2, and “Manual Mode” had *not* been entered, the operator would see now the Treatment Screen in Fig. 4.8, ready to begin the treatment.

4.6.1 Treatment start-up and performing the session (selection by pathology mode)

As already seen for the previous modes, by pressing “Start” the treatment begins, and the screen displayed is the one in Fig. 4.9.

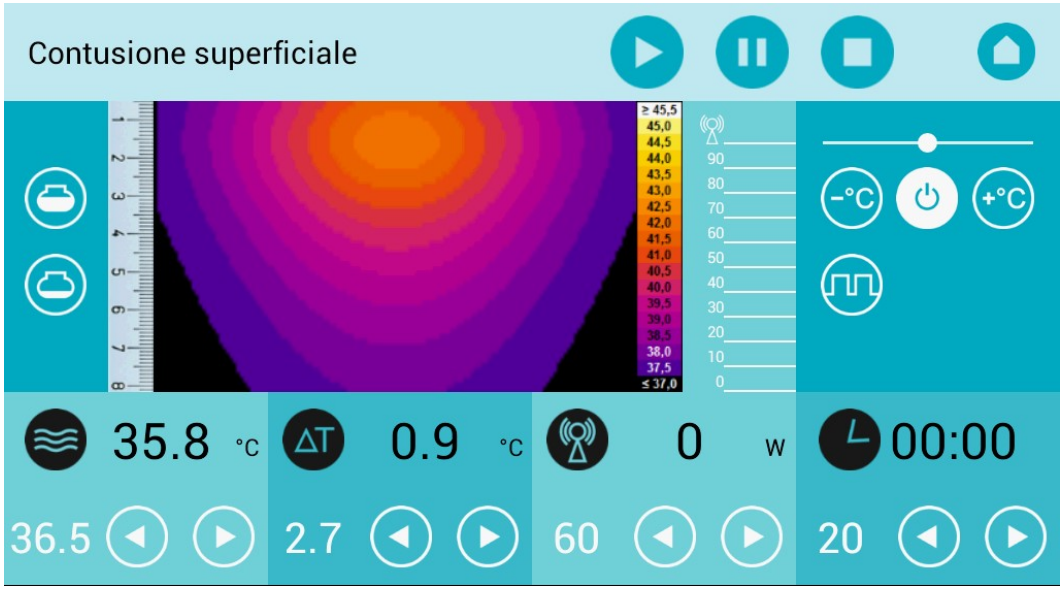


Fig. 4.9 – Treatment started in Selection by Pathology mode

The information label on top is a reminder of the chosen treatment type.

Otherwise, the screen is identical to the corresponding one in “Manual Mode” (see Fig. 3.11) except for the different values of the setup parameters. Here, too, as it happened before hitting “Start”, any action on the six critical keys at the bottom will enter Manual Mode and change on-screen indications accordingly.

The commands behave in the same way than in Manual Mode, and in particular, the treatment can be immediately terminated by hitting “Stop”.

Unless stopped manually, the session will continue until the pre-set time expires.

At that point, to go back to the default, i.e. to the “Option Menu” (“Home”) screen, it is necessary to hit the “Home” button.

4.7 TREATMENT PARAMETERS SETUP: SELECTION FROM ANATOMICAL MODEL

Starting again from the Home ("Option Menu") screen, the operator selects the "Pathology Treatment Setup".

This enters the "Select from anatomical model" screen, Step 1 (Fig. 4.10). Keeping in mind the anatomical district with the greatest amount of damage needing treatment and/or the desired effect, the operator can choose the relative part of the shape that appears in the figure.

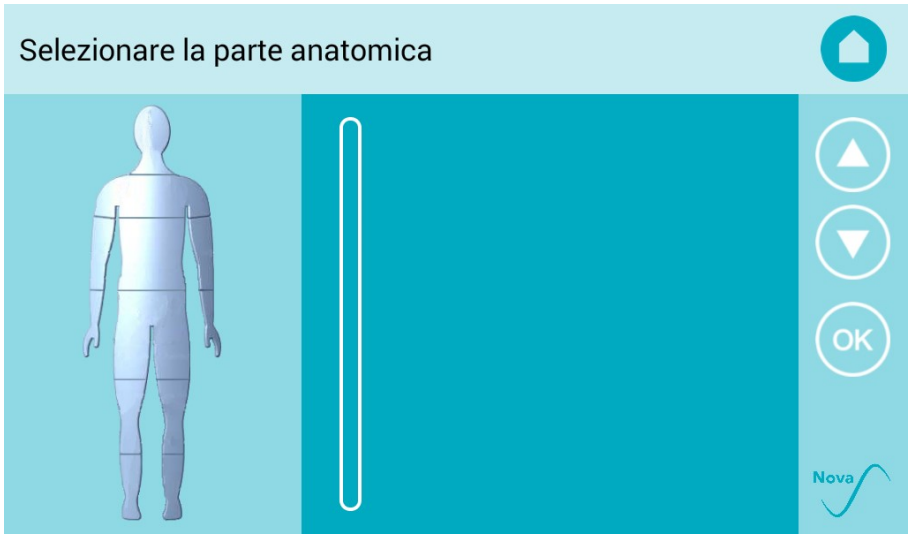


Fig.4.10 – Display ready to select the anatomical district

A menu will appear next to the template (Fig 4.11).

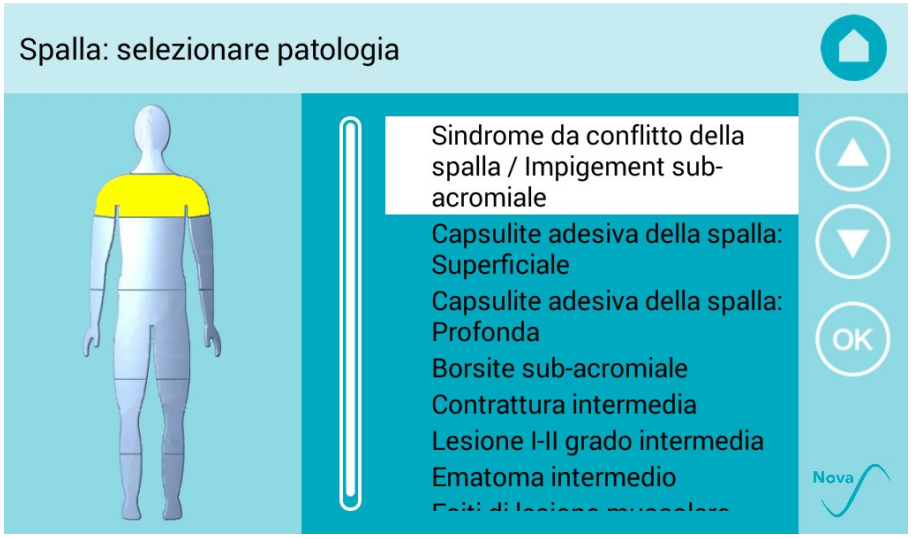


Fig. 4.11 – Display ready to select the Pathology

The choice of one of the proposed options takes place using the keys with the up and down arrows, while confirming with "OK"; this enters the Treatment Framework (Fig.4.12).

Fig.4.12 – Treatment started with Selection mode for anatomical model

The information note above will be consistent with the new situation; for example, if in Step 1 we set the anatomical "Shoulder" district and in Step 2 the item "Shoulder Conflict Syndrome / Sub-acromial Impingement", in the Treatment Panel the writing at the top will recall this and clearly the four numbers of the row further down they will be updated to the values relating to that treatment set. Remember that the machine immediately starts to bring the water to the new required temperature, as always. In general: every time the set water temperature is changed in any way, the machine immediately starts to bring the water to the new value.
The machine is ready to start the treatment, just press Start; consistency checks are carried out internally and if the data is acceptable the processing starts.
As already described for the modes for Pathology and for Structure and Depth, before pressing Start let's analyze what happens if you go to press the following keys:

- The “Bolus” keys can be freely used.
- The “Intensity” area keys can also be used, even if this would be better done once the treatment has begun, and not before, except for the “Modulation” option.
- The two timer keys are also working; even if a markedly shorter or longer treatment makes little sense, this possibility is available to the operator. Using these keys sets up different session lengths; the device will take in the last key pressed.

INSTEAD the six keys: RF power, water temperature and DeltaT are the most delicate because pressing even one only once means to exit from a "pre-packaged" treatment (for example the one for Pathology with which we are dealing at the moment) and switch to Manual Mode by holding the controls in detail. It happens that:

a) The information at the top becomes "MANUAL MODE ACTIVATED" of a striking color, for example orange; it flashes to attract attention and then remains steadily on, indicating that we are in manual mode. To go back to the "Anatomical Model" mode, simply stop the treatment by pressing the STOP button.

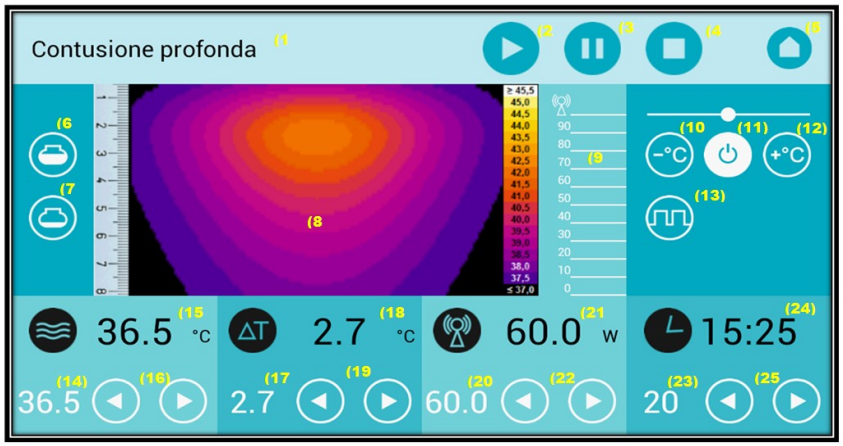
b) As explained in the chapter on Manual Mode, the concept of greater or lesser intensity no longer makes sense, therefore this function is repositioned on Normal (central light) without changing the parameters present at that moment because they were voluntarily set by hand by the operator;

c) at the parameter setting level, there are those that were there before switching to manual mode, except those that we modified by acting on one of the six keys now called and which take the last values set. All this continues to apply even after pressing START, i.e. during treatment.

Suppose now that we have not acted on the RF power, water temperature and DeltaT keys.
By pressing the START key the treatment starts. In our example we will start with the parameters relating to "Shoulder - Shoulder Conflict Syndrome".
The start and execution of the treatment is completely the same as that described for the Selection method for Pathology (see paragraph 4.6)

4.8 RAPID GUIDE

Given the four alternative ways to set up and carry out the treatment, let's go on to describe the fifth button of the Options Menu Panel ("HOME"): "Quick Guide".
Touching the button you enter the Quick Guide Panel (Fig. 4.13) which reproduces the Options Menu marked by numbers referring to a series of explanatory notes that allow the still inexperienced user to become familiar with the use of the Treatment Panel.



(1) Tipo di trattamento caricato
(2) START: inizia un trattamento
(3) PAUSA: mette in pausa un trattamento
(4) STOP:
- se il trattamento non è in corso, resetta i parametri di quel trattamento e riaggiorna il grafico;
- se il trattamento è in corso, lo conclude, resetta i parametri di quel trattamento e riaggiorna il grafico
(5) HOME: chiude la scheda del trattamento e ritorna alla schermata principale

Fig. 4.13 - Demo – Training Menu Screen

As usual, it is possible to go back to the “Option Menu” (“Home”) screen at any moment by hitting the “Home” key, or, if a simulated treatment is underway, by hitting “Stop” and then “Home”.

4.9 SWITCHING THE DEVICE OFF

At the end of the daily sessions, switch NOVA off by pressing the switch on the rear side of the cabinet.

5. MALFUNCTION

The device is fitted with an automatic test feature that provides the therapist with summarized information to troubleshoot problems and resume operation.
If a problem occurs, the related message is displayed in the Status Function Area of the Control Console (lower section).

	Problem	Action carried out automatically by the device	Action carried out by operator
E9	*Reflected RF >15%*		Change the position of the applicator on the part to be treated. If required, use the buttons to fill and deflate the bolus.
E8	*Reflected RF>25%*		Change the position of the applicator on the part to be treated. If required, use the buttons to fill and deflate the bolus.
E7	*Insufficient power*		Potential generator fault. If the problem persists, contact the Technical Support.
E6	*Skin temperature <33°C*	*Interruption of the emission of power*	Leave the applicator in contact with the skin and wait for it to heat.
E5	*Water temperature unstable*	*Interruption of the emission of power*	Wait for the liquid temperature reaches the set value.
E4	*RF generator out of range*	*Interruption of the emission of power*	If the problem persists, contact the Technical Support.
E3	*Faulty thermocouple*	*Interruption of the emission of power*	Verify that the plug of the thermocouple is inserted into the socket (blue connector). Verify that the plug of the thermocouple is inserted in the correct direction. If the error message continues to display, replace the thermocouple. If the problem persists, contact the Technical Support.
E2	*Skin temperature >42°C*	*Interruption of the emission of power*	Verify that the thermocouple is positioned correctly (see text). The error message usually disappears after a few seconds. If this does not occur, switch the device off and on. If the problem persists, contact the Technical Support.
E1	*Water temperature >42°C*	*Interruption of the emission of power*	Wait for the liquid temperature to return within the operating range. If the error message continues to be displayed, contact the Technical Support.
E0	*Insufficient water level*	*Interruption of the emission of power* *Deactivation of the thermo-regulation module*	Add water to the upper part of the temperature regulation reservoir and remove the air from its interior as explained in Chapter 6. If the error message continues to be displayed, contact the Technical Support.

Although evident, please note that these are the foreseeable and interceptable malfunctions (i.e. which can be signaled by the device) but it cannot be excluded that some other malfunction may occur which can only be detected with careful use and maintenance.
The work of the users and maintenance technician therefore remains fundamental for the correct and safe operation of this device.

6. MAINTENANCE

This chapter describes the routine maintenance operations that have to be performed to maintain NOVA in good working order.
It is important to remember that all operations that require the opening of one of the doors must be carried out after the device has been switched off and disconnected from the mains, unless the operation is carried out by qualified and specifically authorized personnel.

6.1 CLEANING THE EXTERNAL SURFACES

Precautions:

- Switch the device off by pressing the push-button located on the rear side of the cabinet.
- Disconnect the 220V power supply plug from the mains outlet. After disconnection, carefully inspect the cable (see paragraph 2.3).
- Do not use solvents or solutions containing abrasive materials.
- Although the device is protected against dripping of liquids, it is always advisable to avoid spilling fluids onto the touch-screen display and the applicator/thermocouple.
- Do not splash fluid on the sides of the device as no special protection is provided for this event.
- Do not use sterilizing systems that use heat/pressure.

The exterior painted surfaces of NOVA can be cleaned using a neutral liquid detergent.
You can clean the Touch-Screen Display with a soft clean cloth that is dry or just moistened in a neutral detergent.
The bolus must be cleaned before each treatment is started and disinfected periodically. Both operations have to be carried out using a non-irritating antiseptic commercial solution purchasable from chemists.

6.2 REPLACING ANTENNA/BAG

The bolus bag must be immediately replaced if broken.

For optimum operation, it is generally advisable to replace the bag after approximately 1000 treatments.

Follow this procedure to replace the bag:

1. Verify that the device does not generate electromagnetic power. If it does, press the STOP push-button.
2. Place the applicator at a medium-high level, vertically oriented so that the two feeder tubes are at the bottom, insert a container of at least 1 liter of capacity in correspondence with the drain pipe to recover the water that could escape due to an excessive charge of the tank and press the bolus emptying button until the bolus bag is almost entirely “sucked” inside the applicator.
3. Switch the device off by pressing the push-button located on the rear side of the cabinet.
4. Detach the applicator from the support arm using the fast-on jack, and place it on a stable, clean surface.

5. Unscrew the two Allen screws recessed in the cover and separate the applicator from the cover itself. Remove the two tubes from the "L" curved hose connectors, after having marked them so as not to exchange them in the subsequent reassembly. Unscrew the ring nut of the RF connector and detach the cable from the antenna. Remove the circular sticker that fixes the thermocouple on the center of the bag.
6. Remove Antenna/Bag.
7. Install a new antenna / bag assembly by reversing the operations of the previous point. Attach the thermocouple to the center of the new bag as it was originally using a new circular sticker supplied.
8. Reattach the applicator to the support arm using the fast-on jack, and position it in a medium-low position, vertically aligned so that the two tubes both face upwards.
9. Turn on the device. The air remaining inside the bag will be replaced by water. Using the bolus filling button, increase the bolus' thickness as desired, usually 2.5 cm when the bolus is resting horizontally on a flat surface.

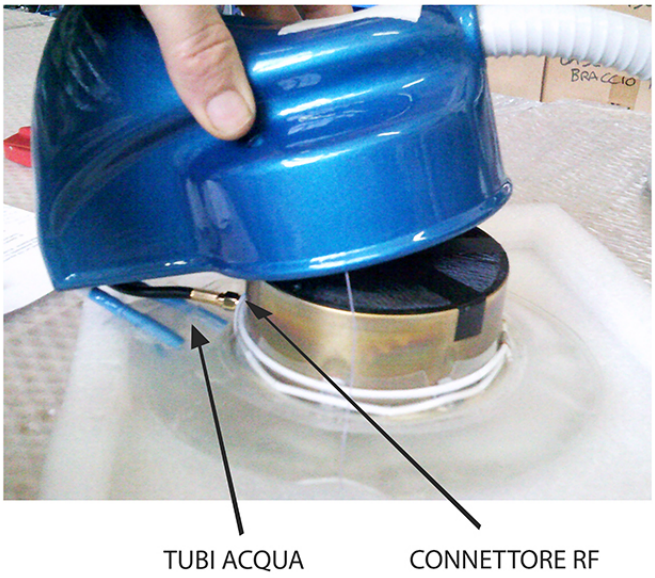


Fig. 6.1 – Sostituzione del gruppo antenna/bag

6.3 INSTRUCTIONS FOR TOPPING THE WATER UP

1. Switch the device off and unplug the 220 V power supply plug.

2. Remove the hemispherical cap located above the hood of the appliance (it is simply put under pressure). Position the applicator just lower than the machine body. Unscrew the hermetic screw cap below with the appropriate tool provided (see photo below) and remove it.

3. Top up the liquid in the tank (use only distill water). The refill quantity ought to be between 200 and 400 cc.

4. Close the screw cap, check that there are no drippings of water around and dry them carefully (now is the time to do it, before reinserting the mains power plug).

5. Place again the hemispherical cap.

6. Plug the 220 V power supply plug and switch the device on by pressing the push-button on its rear side.

7. Adjust the applicator's orientation so that the feeding tubes face upwards to ease removal of the residual air in the bolus.

8. Using the Fill/Empty buttons, restore the desired bolus volume.

6.4 REPLACING THE THERMO REGULATED FLUID

N.B: In order to maintain the guarantee, the thermostatic liquid must be composed of distilled water and an anti-algae product. Before proceeding with the replacement, contact Easytech to find out the type of product or to supply the distilled water and anti-algae solution ready for use.

1. – Position the applicator at a medium-high height and place a container under the overflow sluice tube on the back.
2. – Power on the device and using the bolus emptying control, remove all the water from the bag (it is in this phase that some water may flow from the back tube).
3. – Power off the device and disconnect the power cord. Remove the hemispherical cap from the top of the hood. Disconnect the applicator from the support arm, and detach the arm itself.
4. – Taking it from the handle, bring the device to a vertical position on a raised surface, and place the afore mentioned container below the watertight stopper found behind the cap.
5. – Unscrew the watertight stopper and let the liquid pour out; increase the device's tilt to ease the flow.
6. – Put the device back in the horizontal position and fill the reservoir with 1l of deionized water, or other liquid recommended by Easytech.
7. – Screw back the watertight stopper, dry carefully any spillage and place again the hemispherical cap.
8. – Power on the device and adjust the applicator's orientation so that the feeding tubes face upwards, to ease removal of the residual air in the bolus.
9. - Using the Fill/Empty buttons, restore the desired bolus volume.

6.5 ROUTINE MAINTENANCE INSPECTIONS

This device has been specifically designed to minimize maintenance during use, which is an essential requirement for physiotherapy applications.
However, even if no major fault occurs, it is critical to perform all the required maintenance and inspection operations in order to ensure a perfect efficiency, also in consideration of the fact that the accuracy of this device, as of any other medical device, critically affect safety and operating results.
In addition to the regular inspections specified in current standards that apply to equipment used in Type A clinical environments and areas used for medical applications, the manufacturer recommends also the following maintenance schedule.

- Once a year or every 1,000 sessions, if this number is reached in less than a year: replacement of the bag to be performed by the technical support or user.
- Once a year: replacement of the temperature regulating liquid to be performed by the technical support or user.
- Once a year: calibration of the temperature control channels to be performed by the technical support or user. If the results of the calibration show that it is necessary to perform an adjustment, this shall have to be done by the Technical support.
- Once a year: electrical safety test to be carried out by Easytech (which requires the return of the equipment) or by a specialized laboratory (in this case it may not be necessary to move the device)
- Every six years: general inspection carried out by Easytech, which includes all the annual and triennial operations described above.

7. TRANSPORTING THE DEVICE

NOVA can be shipped and handled in either vertical or horizontal position without special precautions, except avoiding the possibility of the liquid inside freezing. If there is a risk of remaining at temperatures below 0°C long enough for this to happen, care must be taken to empty the device (see paragraph on “Fluid replacement”)

For convenience, it is advisable to detach the applicator from the spherical joint, then remove the arm by unscrewing the two fixings on the body.

In order to separate the applicator from the spherical joint, it is necessary to loosen the knob on the joint, gripping the applicator to remove it until the bushing is removed from the cylindrical shaft.

NOVA can be easily transported with the trolley bag (optional).

7.1 ENVIRONMENTAL TRANSPORT AND STORAGE CONDITIONS

In case of longer storages, or storage with the possibility of temperature falling below 0 °C, it is advisable to empty the thermoregulation circuit.

The storage conditions listed below apply to the device with empty thermoregulation circuit.

- Environment temperature: [-10 ÷ + 50] °C
- Relative humidity: [30 ÷ 75] %
- Atmospheric pressure: [700 ÷ 1060] mbar

Start-up the device after transport and/or storage:

Once the thermostatic liquid circuit has been recharged, the appliance is normally ready for ignition. Only if it is known or suspected that it has been subjected to extreme conditions of humidity and condensation, before turning it on, keep it 24 hours in operating environmental conditions.

8. PACKAGING

It is recommended to keep the original packaging. In case you miss, place it in a special cardboard box and then choose a specialized courier for this type of transport.

9. DISPOSAL OF THE DEVICE AT THE END OF ITS LIFE CYCLE

The disposal of the device generally consists in simply replacing it and in returning the old one to the manufacturer for disposal.
If this is not feasible, it is necessary to dispose of the unit in accordance with current law provisions concerning electric and electronic equipment (Directive WEEE 2012/19/UE).

10. APPENDIX 1 – LABELS

Class B in accordance with CEI EN 60601-1

This label is placed on the applicator

"Warning"

This label is placed next to the 220 V mains switch

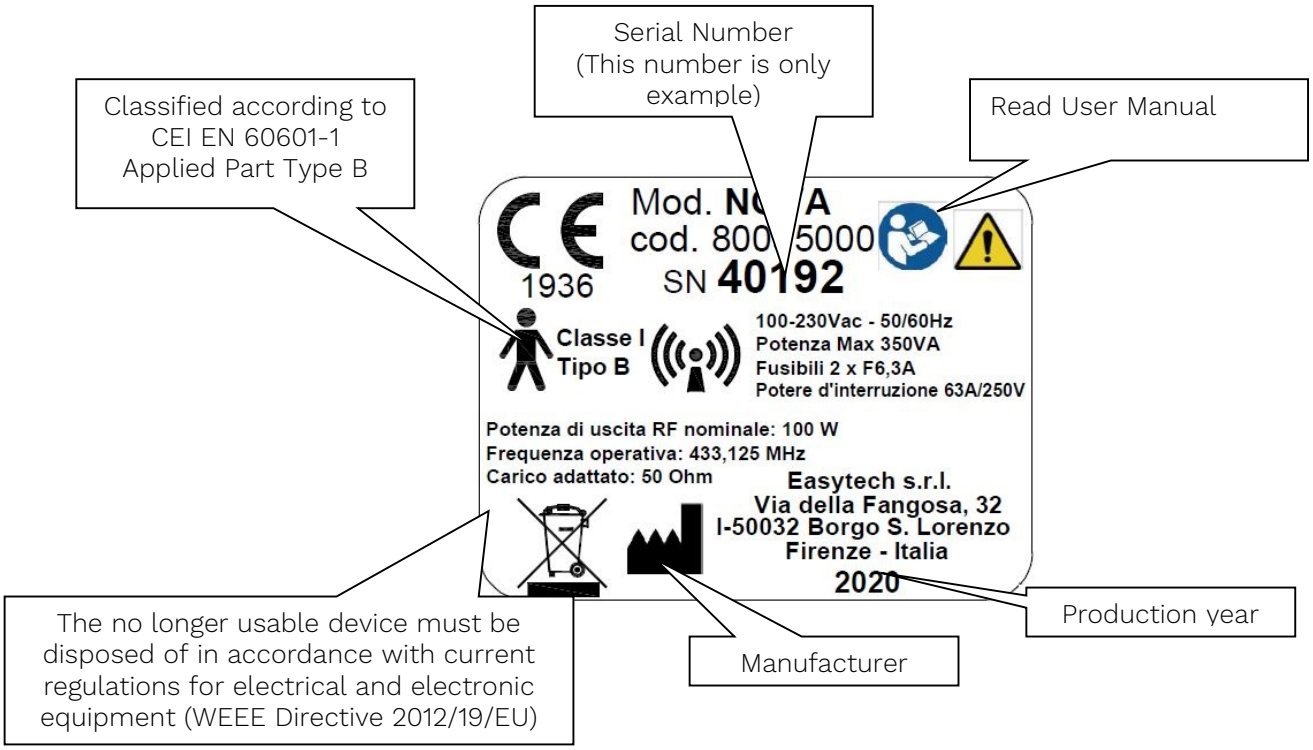
Non ionizing radiation

This label is placed on the applicator

Equipotential node

This label is placed on the left side of the device, near to the equipotential node

Device plate – It is located on the back of the machine



11. APPENDIX 2 – THE BIOPHYSIOLOGY OF HYPERTHERMIA

11.1 USE OF HYPERTHERMIA FOR PHYSIOTHERAPY

It is known that heat is a therapeutic principle used to treat several muscular-skeletal pathologies. It is employed for several applications that range from sports traumatology to degeneration caused by aging. Results are however traditionally controversial, that is sometimes good and sometimes disappointing. This depends mainly on the approximate method used to apply heat.
Hyperthermia is able to overcome the limits and defects of other thermal therapies because it guarantees a more accurate application of heat as compared to traditional techniques.
The hyperthermia used for therapeutic purposes is a type of a thermal therapy that enables to treat injured tissues by using the temperature range in which heat proves to effectively aid physical rehabilitation.
This characteristic of hyperthermia is the element that enables to achieve more effective results as compared to traditional methods, although it poses complex theoretical and technical challenges, which are easily inferable by the description of the device itself.
The temperature range that can be used for therapeutic purposes is comprised between 38 and 45.5°C, though specific areas and pathologies often require narrower ranges and higher temperatures, usually between 41°C and 44°C.
Temperatures above 45°C cause more damages than benefits because the organism attempts to reduce the temperature to ordinary values by increasing the blood flow in the heated volume. This fact clearly shows the delicate balance between the device used to induce hyperthermia and the tissues that are treated, in addition to highlighting the importance of continuously monitoring the temperature of all the areas where temperature is increased.
On the other hand, the greater blood flow (hyperemia), which increases in function of temperature, is one of the elements that most significantly influences the "self-recovery" functions of the organism, which means that it is therefore essential to apply an optimum amount of heat depending on circumstances.
Other types of thermal therapies do not allow you to achieve these results and thus do not pose this problem.
Hyperthermia optimizes the typical biological responses of the organism to thermal therapies, specifically causing the following:

- Increase of circulation originating from the dilatation of vessels
- Increase of the cell metabolism
- Antalgic action caused by the increase of the pain threshold as a result of the application of heat
- Antiflogistic action with consequent reduction of inflammation, edemas and exudates
- Reduction of the rigidity of limbs and of fibrous tissues due to the alteration of the tissue stiffness
- Reduction of muscular spasms

At an application level, hyperthermia effectively replaces (due to its greater efficiency and the shorter recovery times) many of the "ingredients" that are normally prescribed by doctors during rehabilitation, such as:

- All heat therapies, except in cases in which it is necessary to simultaneously heat all the body with a "total body" therapy or thermal bath

- Ultrasounds in the vast majority of cases
- Laser in the vast majority of cases
- Magnetotherapy in the vast majority of cases

Alternatively, it also enables to significantly reduce doses, for example of anti-inflammatory or pain killing drugs, with a consequent reduction of collateral effects.

11.2 BIO-PHYSIOLOGICAL CONSIDERATIONS

11.2.1 Effects induced by heat

When hyperthermia is used for physical rehabilitation purposes, heat is generally applied to a small part of the whole organism only. Hyperthermia is however a very complex procedure because the heat produced causes several bio-physical alterations.
The local effects are also extended to other areas of the organism by means of chemical and nervous messages, resulting in additional reactions that modify the treated volume.
The induced effects do not directly originate only from the temperature increase (for example from 37°C to 42°C), but are also influenced by the duration of the temperature increase, the rate at which it is increased, the interval of time between two subsequent temperature increases, the extension of the heated area, and the ratio between the heating level of the area to treat and the neighboring ones.
All the phenomena that occur are so interconnected between one another that they are difficult to analyze and describe in detail.
To simplify the issue, let's suppose that the treated volume is exposed to one temperature increase only and that this condition is maintained for a specific amount of time. Although this condition does not adequately reflect actual conditions, it does take into account the elements that influence most significantly hyperthermia used for physical rehabilitation purposes.
From a thermal point of view, it is possible to divide the hyperthermia session into three distinct stages:

- The period in which temperature increases up to the desired value
- The period during which temperature is maintained at the pre-set value
- The period (at the end of the actual session) during which temperature is naturally decreased down to the physiological value

The resulting effects tend to follow these three phases, but occur gradually, with a specific delay and following given rhythms. Therefore, the timings in the following description are approximate only, even in consideration of the fact that phenomena are interrelated and it is difficult to separate causes from effects.
The increase of temperature (which occurs at a rate that reflects the amount of heat applied) causes an increase of the blood flow (Fig. 11.1) due to the dilation of the artery and capillary vessels. Its main goal is to cool the area because the incoming blood has a temperature (37÷37.5°C) below that of the treated tissue (i.e. 40°C).,

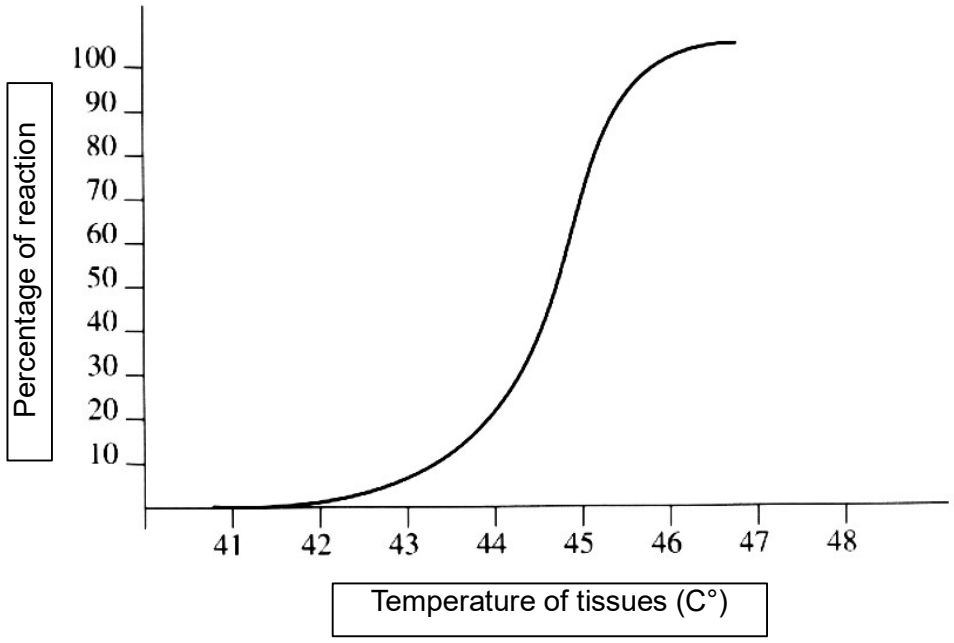


Fig. 11.1 – Increase of perfusion in function of the temperature of the tissue

The change of the flow is caused both by a direct effect, that is by the increase of temperature, and by reflected mechanisms. The latter involve thermal receptors that, if stimulated by heat, trigger local axonic reflexes and more complex central responses that control in part of the hypothalamus temperature control.
Within a short interval of time and in parallel, the change of rate of all cellular reactions, caused by the increase of temperature, causes the metabolism to change. A modest heating produces a slight increase of metabolism, while higher temperatures cause significant variations that change the resulting products (it is sufficient to consider that the rate of reactions does not always increase by same amount), ultimately leading to the irreversible transformation and/or denaturation of proteins, enzymes and catalysts and to biological damage. The phenomenon worsens as the exposure time increases, finally causing the necrosis of the cells.
These perturbations (which are caused by a higher release of substances or by an abnormal qualitative release of substances) produce chemical messages that cause the dilation of vessels.
The most frequent phenomena are a greater perfusion and local drainage.
These in turn increase the activity of the lymphatic system, responsible for removing the "waste" that cannot be removed, due to its size and bio-physical characteristics, by the reabsorption of blood capillaries; for example proteins and other particles that can sometimes be found in the interstitial liquid and in the fluids of virtual spaces of pathological or traumatic origins.
The increase of flow at a local and regional level produces a percentage increase of micro-circulation (higher number of simultaneously open capillaries per volume unit), which slightly decreases the incoming pressure and the rate within each active capillary. The overall effect of these phenomena is an increase of the flow rate and amount of blood in the treated volume (hyperemia). This consequently increases the amount of gaseous exchanges, i.e. the exchange of metabolites and ions between the vessel bed and the perivascular and interstitial spaces, thus increasing the removal rate of the cellular catabolism and necrotic waste produced by the lysis of degenerated cells.
The reduction of the blood flow rate also stimulates margination and diapedesis, through the

walls of the vessels, of the granulocytes and macrophages responsible for inflammatory and tissue recovery processes. This in turn causes a larger amount of cells to migrate towards the tissues with lesions.
However, maintaining a high temperature for a long period of time could irreversibly block local circulation. This phenomenon usually starts with a significant margination of neutrophil granulocytes and the swelling of erythrocytes, which in time causes the obstruction of vessels. The delicate endothelial tissue of capillaries, which is particularly sensitive to heat, is not able to tolerate the double mechanical load, is damaged and causes circulation to stop. As this situation must obviously be avoided, it is essential to monitor the temperature of the treated volume.
The action of heat also modulates the activation of the immune cascade, though with different effects, as some factors are enhanced while others reduced.
The increase of temperature increases the amount of free O2 due to the fact that it is easier to separate oxygen from hemoglobin.
The higher amount of free oxygen is essential to meet the higher metabolic needs of cells, in which the increase of temperature has caused an increase in the number and rate of chemical and biochemical reactions, which can be satisfied only by means of a higher amount of O2 and metabolites.
As explained above, the increase of temperature causes the death of the most damaged cells (cell killing). Injured cells or cells damaged due to pathological or traumatic reasons have a reduced resistance to additional stressful stimuli, consequently an increase of temperature is enough to determine their necrosis.
The necrosis of cells causes the release of chemotactic substances, that is of growth-factors that provide a powerful regeneration and/or recovery stimulus.
In the interval of time during which the hyperthermia level is maintained constant (despite the attempt of the organism to lower the temperature), the enhanced perfusion stabilizes (Fig 11.2), resulting in the standardization of all the phenomena in progress. Most of these phenomena tend to produce more evident results as the exposure to heat increases.

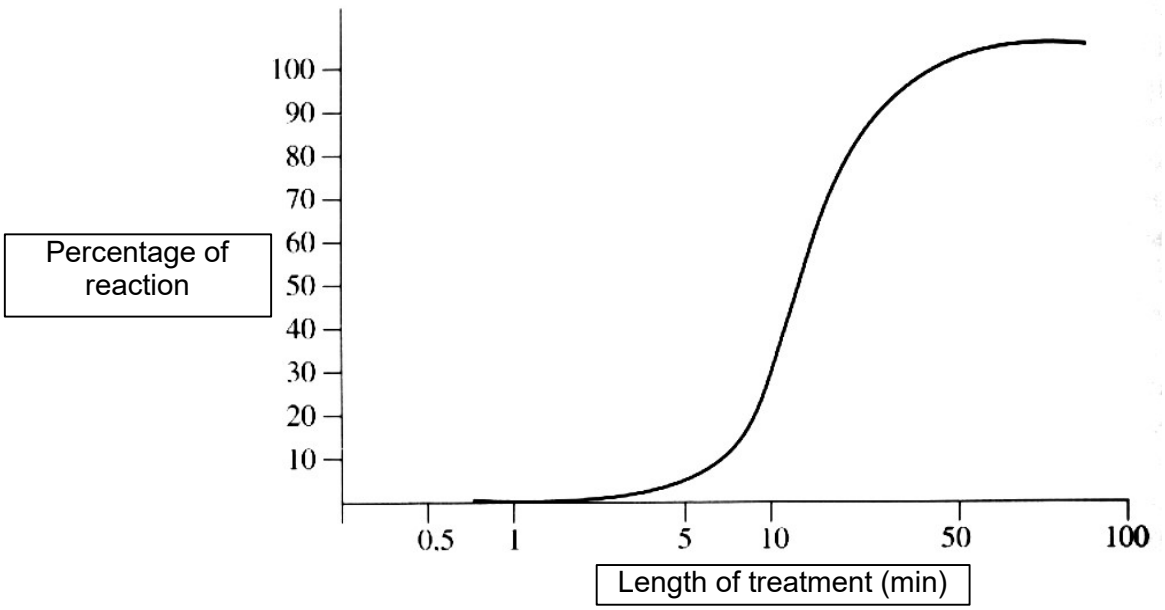


Fig. 11.2 – Increase of perfusion in function of the length of the treatment

On the other hand, as explained above, the therapeutic temperature "window" (that is the range of temperature that can be used for therapeutic purposes) is rather limited and generally equivalent to 38÷45.5°C). The upper range (that is temperatures above 41°C), which ensures a greater effectiveness, tends to produce undesired collateral effects after very short times. Because of these phenomena, therapists tend to maintain the length of the session around 20 minutes, depending on the actual requirements of the physical therapy, and to change the temperature of the tissues in function of the site and pathology.
At the end of the session, that is after the heating process has been interrupted, the internal temperature gradually returns to its normal value because of circulation. It is interesting to note that a small residual increase of temperature (approximately 0.5°C) can generally be observed for a few hours, probably as a result of the attempt of the increased metabolism to self-support itself. Although this phenomenon may contribute to the reparation of tissues, there is no evidence to prove the usefulness of extending the length of the treatment after temporarily covering the treated area with a thermal insulation.
Even the interval of time between two sessions is influenced by the procedure used to apply the treatment and consequently by the reactions induced on the organism.
After the heating produced by hyperthermia, which is directly influenced by the intensity of hyperthermia itself, the healthy cells that have survived to the cell-killing (the vast majority) acquire a greater resistance to heat, as a result of the metabolic changes they have undergone (such as the production of "heat shock proteins"), and are able to maintain it for longer periods of time, that is from one to five days. This also lessens the reactivity, for example a less evident increase of perfusion, in presence of the increase in temperature. This phenomenon, which is described in very simple terms, is called "thermal tolerance". The complexity of the hyperthermia phenomenon is demonstrated by the fact that from this simplified description it would appear that several repeated sessions are generally more effective than less frequent ones.
In consolidated practice and when the treatment parameters specified in the guidelines are used, the optimum frequency generally appears to be a daily one.
It is useful to note that in the example we have assumed that it is implicitly possible to heat any part of the tissue regardless of its depth, that is without interacting with the layers that are interposed between the treated volume and heating source. These treatment conditions can be achieved only with hyperthermia equipment, which have finally enabled therapists to solve issues that initially appeared without solution and obtain conditions that are similar to those assumed. This is true in particular when it is necessary to apply the heat in depth.

11.2.2 Effects of the heat on the muscular and skeletal system

Heat does not only produce specific effects on cells and tissues effects, like the ones described so far, but also more macroscopic effects.
The increase of temperature increases the extensibility of collagen, thus enabling slight plastic and elastic deformations. This means that in appropriate conditions it is also possible to obtain permanent deformations (elongation, sliding) of structures that are normally very stable at a physiological temperature, like tendons, ligaments and capsules (Fig. 11.3).

This effect is even more evident if we think of the molecular structure of collagen tissues, where collagen and elastic fibers are organized in different layers. These proteins are in fact linked by means of complex chemical bonds. Consequently, a targeted increase of temperature weakens and stimulates the expansion of the fibers on one another, without subjecting the involved structures (tendons, ligaments and articular capsule) to an excessive increase of stress as a result of the forced stretching.

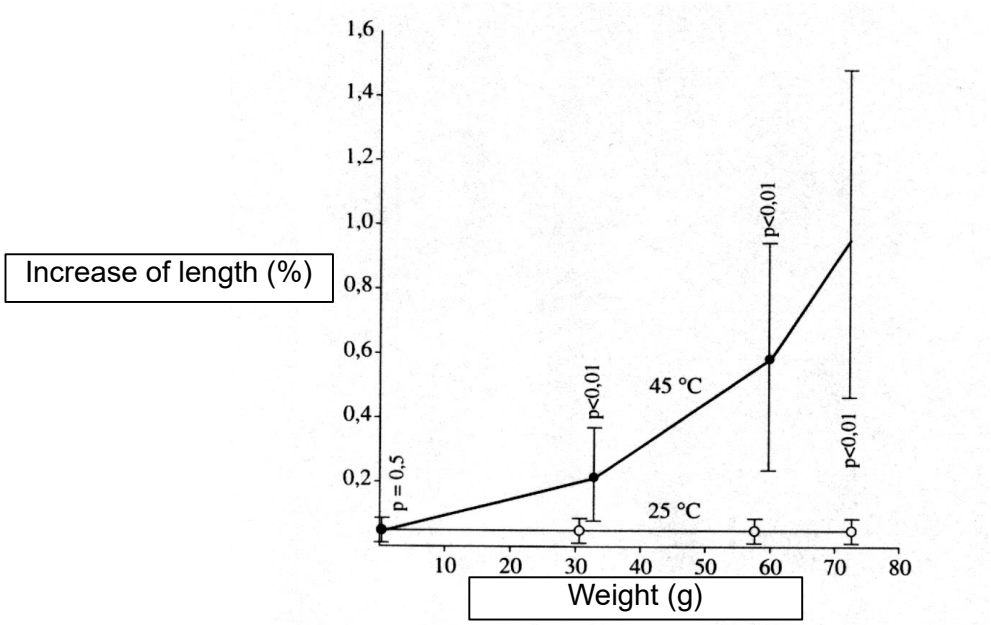


Fig. 11.3 – Residual elongation of the tendon measured after the increase of temperature at 45 and 25°C

This phenomenon is naturally very important as it enables to dimensionally recover a tissue structure that cannot normally be stretched, and also treat articular rigidity where the therapeutic effect consists in recovering the range of movement by enhancing smoothness and reducing pain.
To achieve these results, it is important to apply the heat while mechanically stretching the treated tissue. In other words, it is important to maintain a close link between the actual hyperthermia treatment and kinesitherapy, the latter being used to produce a prolonged and continuous stretching in cases in which it is necessary to obtain a significant and long-term dimensional recovery of the limb. Mobilization with gradual stretching is instead used (generally at a later stage) to improve the fluidity of the movement within the range of movement that has already been achieved.
If exposed to heat, the muscular tissue, which contains several vessels and a high number of capillaries, significantly increases the amount of available blood thus producing the metabolic effects described above.
The increased blood flow enhances contractility as it increases the activity of the ATPase enzymes, which are able to divide the phosphor bonds and thus release a greater amount of energy.
The increased blood flow also normalizes the pH, which directly influences the activities of several enzymes including ATPase enzymes.
The increased blood flow increases the amount of ions and of sodium in particular, contributing also to the standardization of electrolytes, which, when unbalanced, are the main cause of cramps.
Muscles also contain a delicate and complex connective support system, with a base molecule consisting of collagen. Consequently, the increase of heat stimulates the ability of the myofibrils to slide onto one another, while simultaneously enhancing the overall extensibility and elasticity of muscles. It is sufficient to note that stretching is usually easier if

the muscle has been warmed up.
While the myorelaxing effect is typical of thermal therapies, it is more evident in hyperthermia due to the higher temperatures used and the greater treatment depths.
The reduction of muscular spasms is the result of a reflex mechanism that involves several complex receptorial structures, like the Golgi tendon, neuromuscular fuses, gamma fibers and secondary afferent fibers.
The Golgi tendon and neuromuscular fuses contribute to the adjustment of the muscular tone and to the degree of tendon stretching.
Even in standard conditions, the Golgi tendon inhibits muscular contraction. However, the exposure to heat increases its discharge frequency, thus accentuating the contraction inhibition.
Neuromuscular fuses, with their basal discharge frequency, are instead responsible for controlling the muscular tone. Exposure to heat reduces the discharge frequency, thus producing the relaxation of the muscle.
In other words, the application of heat to the neuromuscular structures responsible for controlling contractility causes muscular relaxing and inhibits contraction.
The reduction of inflammatory infiltrates, drainage and the removal of exudates and edemas is the result, as explained above, of the increase of capillary permeability that stimulates exchange, and of a mechanical drainage that is supported by the increase of the blood flow.

↑ Blood flow
↑ Extensibility of collagen
↑ Contractile efficiency of the muscle
↓ Articular rigidity
↓ Muscular spasm
↓ Inflammatory infiltrates, edema, exudates
↓ Pain

Fig. 11.4 – "Macroscopic" effects of heat on the muscular and skeletal system

As far as the antalgic effect is concerned, heat generally inhibits or rather reduces the discharge frequency of the thin afferent fibers, which are those that generally transmit pain impulses.
The positive effect of heat on pain originating by the anatomical structures of the locomotory system has been known for a long time and was exploited also in the antiquity. In this sense hyperthermia has not introduced any significant innovation, except for a greater effectiveness.

11.2.3 Physiopathology of traumatic responses

In order to correctly exploit the effects of heat, it is obviously necessary to possess a good knowledge of the anatomy of tissues.
Tissues differ from one another because of their characteristic anatomic structure and vascularization.
Consequently the effect of heat on different tissues varies, along with the times, length and application procedures.
Because of the different anatomy and vascularization, tissues also have different healing times.
Skin, for example, is able to repair a superficial lesion, with a significant loss of substance, though the regeneration of the epithelium, while this behavior is very limited or completely absent in nerve or cartilaginous tissues.
Despite their differences, all tissues respond to pathogen agents or traumas in the same way, that is through inflammation.

This basic and essential form of reaction is common to all tissues, regardless of whether the tissue is formed by muscles or bones. The final results of the inflammatory process can however be very different.
An acute inflammatory response is generally constituted by a series of common biological events, characterized by four main phenomena: redness, temperature increase (increase of temperature as compared to the neighboring area), tumefaction and pain.
There is also a fifth sign of inflammation, which is particularly important for physiotherapy and rehabilitation purposes, that is functio laesa, that is the impairment of normal functions.
If we were to define inflammation, we would say that it represents the series of local alterations of the blood flow, vessels and tissues that occur as a result of a pathogen stimulus, whose aim is generally that of removing the irritant action.

The latter is generally represented by local mechanical, thermal, chemical, electric, radiant and infective stimuli or of other origin.
The most interesting biological aspect is however the succession of stages, which are coded and geared towards one goal, that is recovering homeostasis through a set route that generates a temporary unbalance (Fig. 11.5).

Days 0-3 Days 2-4	Vasomotorial reactions + exudate + leukocytes Macrophages for phagocitosis + fibroblasts + new vessels	Acute phase
Days 5-6	Granulation tissue and new vessels, maximum expansion	Sub-acute phase
Days 6-28	Synthesis of collagen and reduction of new vessels	Synthesis phase
Days 28-120	Reorganization and remodeling of the new collagen	Remodeling phase

Fig. 11.5 – Inflammation phases

As the administration of heat further disturbs the balance during the inflammatory process, it is important to follow specific requirements taking into consideration not only the type of tissues but also the pathology and the inflammation phase to avoid worsening the condition instead of therapeutically treating it.
If we were to summarize the different stages of the inflammatory process, we could say that the first phase, that is the acute one, which starts when the tissue is injured, lasts for the first 2-3 days.
In this phase, vasomotorial reactions are the most important ones because the initial stage resulting in the dilation of vessels is followed by a restriction and closure of vessels.
This local circulation dynamics aims at conveying a large amount of blood, and serum that, due to the enhanced capillary permeability, expands externally the lysins required to bind and neutralize bacteria and the toxins produced by the latter, by diluting the concentration of pathogen agents and inundating the area with agglutinins and precipitins.
The numerous fibrins form a tightly knit grid that traps the above-described pathogen substances.
In the final stage, we see the growth of leucocytes, that is white cells, in the injured area. These are responsible for causing the lysis of bacterial or necrotic cells.
The subsequent phase that is directly linked to the previous one is the sub-acute phase.
This phase is characterized by the proliferation of granulation tissue, that is the temporary tissue that controls the tissue reparation processes.
This tissue is characterized by the presence of other phagocyte cells, that is the macrophages, which "remove" cell waste from the tissue and injured cells, or by leucocytes that eat bacteria and viruses.

This is also the phase in which new blood vessels are formed. Their function is to adduct new substances from the flow when the anabolic phase starts. Blood may also come into contact with immunocompetent cells of the flow, which leads to the creation of antibodies.
This phase, which covers days 5 and 6, is also characterized by the presence of mesenchymal cells (that is fibroblasts, osteoblasts, etc., depending on the tissue), which are largely responsible for synthesis and deposition of collagen fibers.
This is the beginning of the synthesis phase, during which the loss of tissue substance is replaced through the deposition of connective tissue, which gradually acquires the same behavioral and functional characteristics of the tissue it has replaced.
The synthesis phase starts approximately around the 6th day of the inflammatory process and lasts up to the 28th day. In the initial period, collagen is synthesized at a high rate and metabolism is increased and supported by the greater blood flow. Over the days, the collagen synthesis decreases along with the number of vessels that occlude and disappear.
The final phase is the so-called remodeling phase, that lasts from the 28th day to the 120th. This is characterized by spatial reorganization and by the remodeling based on the strength and load lines of newly synthesized collagen fibers. Its aim is to allow the recovery of the original functionality.
The following detailed analysis of the inflammatory process enables us to highlight some important aspects that should also be taken into account when applying heat:
1) The use of heat in the acute phase (days 0-3) is generally not recommended because of the presence of significant vasomotorial phenomena. Traumatic injuries often cause the rupture of vessels and bleeding. Thus, the vessel dilation effect produced by heat would interfere with the ordinary coagulation process. This is particularly true of muscular tears, where heat would prevent the bleeding from healing.
2) In the sub-acute phase (days 3-6), that is when the vasomotorial phenomena have stabilized, it is possible to start applying heat to the tissues, though very carefully and using modest temperatures and gradients, because the resulting reflected responses could awaken the pains and inflammation.
3) In the synthesis phase (days 6-28), the use of heat is particularly effective. The initial critical phase is in fact followed by a formation of new vessels and capillaries that can indirectly respond to thermal stimuli. Supporting the blood flow in a tissue where significant synthesis processes are occurring and where the basal metabolism is higher, is clinically correct because it aids the reparation of the tissue.
4) The same applies to the remodeling phase (days 28-120 and beyond) because, although the new vessels have definitely disappeared, it is still possible to increase the blood flow at a local and regional level, thus preventing the formation of conditions that could cause degeneration phenomena originating from a poor vascularization.

12. APPENDIX 3 – BIBLIOGRAPHY

A. V. Guy, J. F. Lehmann, J. B. Stonebridge "Therapeutic Applications of Electromagnetic Power" Proceedings of IEEE, Vol. 62, No. 1, January 1974

Detailed introduction on the selection of the frequencies and most appropriate technical solutions for therapeutic applications, essentially in function of the developed heat and in accordance with the state-of-the-art technologies available at the time of publishing. The therapeutic action is essentially compared with the heat developed. No reference is however made to hyperthermia, its characteristic requirements of carcinogenic origin, and to its potential use for physical rehabilitation. Guy and Lehmann were the main promoters of the use of hyperthermia for tumors in the sixties and seventies, which was made possible thanks to the progresses in the electromagnetic field.

F. J. Kottke, G. K. Stillwell, J. F. Lehmann "Trattato di terapia fisica e riabilitazione" Vol. 1 – Verduci Editore (English version: Kottke-Lehmann "Krusen's Handbook of Physical Medicine and Rehabilitation" – Saunders)

Accurate description of the effects and therapeutic applications of heat on several tissues and parts of the body, even in functions of temperatures reached. No reference is made to hyperthermia for physical rehabilitation purposes, but the requirements described clearly emphasize the inadequacy of hyperthermia equipment. The qualitative transition occurred with the introduction of hyperthermia equipment derived from devices used for the treatment of tumors.

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DECLARATION OF CONFORMITY

The product

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complies with the provision of Annex I of Council Directive 93/42 EEC of 14 June 1993 concerning medical devices, published in the Official Gazette of the Italian Republic on 25 October 1993 and acknowledged in Italy through Legislative Decree No.46 on 24 February 1997 and subsequent amendments and additions.

The product is a Class **IIb** active medical device in accordance with Rule 9, Annex IX of European Directive 93/42/ECC.

Borgo San Lorenzo, 1/3/2019

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